GE Healthcare

Senographe DS Acquisition System

Quality Control Tests

CE 0459

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Revision 1

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X-ray Warning

WARNING

X-ray equipment is dangerous to both patient and operator unless measures of protection are strictly observed

Though this equipment is built to the highest standards of electrical and mechanical safety, the useful x-ray beam becomes a source of danger in the hands of the unauthorized or unqualified operator. Excessive exposure to x-radiation causes damage to human tissue.

Therefore, adequate precautions must be taken to prevent unauthorized or unqualified persons from operating this equipment or exposing themselves or others to its radiation.

Before operation, persons qualified and authorized to operate this equipment should be familiar with the Recommendations of the International Commission on Radiological Protection, contained in Annals Number 60 of the ICRP, and with applicable national standards and should have been trained in use of the equipment.

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Foreword

1 Applicability of manual

This document “QC Manual” constitutes an element of the Quality Assurance Plan (QAP) of the mammographic facilities. It describes Quality Control (QC) Tests for the Senographe DS, which constitutes the digital image acquisition sub-system of a full-field digital mammography (FFDM) system.

Application of this manual is MANDATORY for facilities subject to the rules of the United States Mammography Quality Standards Act (MQSA).

Application of this manual is RECOMMENDED for facilities in locations not subject to the rules of the MQSA.

Note:

Parts of this document are applicable only to facilities subject to the MQSA. These paragraphs are shown *in italic text* and remain in English, regardless of the language of the document.

2 Regulatory considerations

In facilities subject to the MQSA, the procedures in the document “Senographe DS Acquisition System QC Manual” must be followed. Failure to follow these quality assurance procedures can result in loss of MQSA certification at facilities subject to U.S. regulations.

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ALTERNATIVE STANDARD ON USE OF TEST RESULTS

An amended Alternative Requirement to 21 CFR 900.12(e)(8)(ii)(A) was approved by FDA on 31 August 2007. The original alternative requirement dealt with the action to be taken by an operator upon the failure of a test in the QC plan of a GE Senographe™ full-field digital mammography system. The amendment separates the actions into those associated with an image acquisition system and those associated with an image display system. The actions to be taken in regard to the QC plan for the GE Senographe DS Acquisition System are as follows:

21 CFR 900.12(e)(8): Use of test results.

For the image acquisition system

(i) If the test results for the image acquisition system of the FDA-approved GE full-field digital mammography (FFDM) equipment fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammographic images are acquired using the image acquisition system that failed any of the following tests:

- *(1) Monitor cleaning for the Acquisition Work Station (AWS)*
- *(2) Flat Field Test*
- *(3) CNR Test*
- *(4) Phantom Image Quality Test for the AWS*
- *(5) MTF Measurement*
- *(6) AOP Mode and SNR Check*
- *(7) Visual Check List*
- *(8) Compression Force Test*
- *(9) Average Glandular Dose*
- *(10) Post-move, Pre-examination Tests for a mobile FDA-approved GE FFDM*
- *(11) Sub-system MTF Measurement*

(B) Before any further films of mammographic images are printed or processed using the component of the FDA-approved GE FFDM equipment that failed any of the following tests:

- *(1) Phantom Image Quality Test for the Printer*
- *(2) Viewbox and Viewing Conditions Test*
- *(3) Printer QC*

(C) Within 30 days of the test date for the following tests:

- *(1) Repeat Analysis*
- *(2) Collimation Assessment*
- *(3) Evaluation of Focal Spot Performance*
- *(4) Exposure and mAs Reproducibility*
- *(5) Artifact Evaluation; Flat Field Uniformity*
- *(6) kVp Accuracy and Reproducibility*
- *(7) Beam Quality Assessment (Half-Value Layer Measurement)*
- *(8) Radiation Output*
- *(9) Mammographic Unit Assembly Evaluation*

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3 Scope of this manual

The scope of this document is the quality control (QC) tests to be applied to the Senographe DS, the image acquisition and pre-processing sub-system of an FFDM system. QC tests to be applied to the display systems intended for clinical image review are included in a separate manual.

Two kinds of QC tests are listed:

1. QC Tests specific to Digital Mammography.
   Procedures for performing these tests are extensively described in this manual.
2. QC Tests not specific to Digital Mammography.
   These are tests which are already performed on Analog Mammography systems and which still apply for some features of the Senographe DS.
   Procedures for performing these tests are not extensively described in this manual

4 Overview of this manual

This Quality Control (QC) Manual consists of three main sections:

1. QC Tests for the Radiologic Technologist.
2. QC Tests for the Medical Physicist.
3. Guidance.

The QC Test sections contain full descriptions of test procedures, testing frequency, and action limits for tests specific to Digital Mammography. For tests not specific to Digital Mammography, testing frequencies and action limits are provided but procedures are not fully described.

The Guidance section contains recommendations on procedures for performing tests not specific to Digital Mammography, as well as supplementary material for user information. References to this section are made at appropriate points in the QC Tests sections.

5 Acknowledgment

Some elements of the QC Tests have been reprinted with permission of the American College of Radiology, Reston, Virginia.

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Chapter 1 QC Tests for the Radiologic Technologist

1 Introduction

QC tests are simple checks which ensure that the Senographe DS system is operating to its design standards. They are designed to detect any changes in settings which might compromise image quality, as well as any deterioration in equipment performance over time.

QC tests for the Senographe DS are described in the following sections:

- Section *3 Monitor Cleaning on page 15*.
- Section *4 Flat Field and Phantom IQ Tests on page 16*. Checks for consistency of image quality.
- Section *5 CNR and MTF Measurement on page 21*. Checks for consistent production of good contrast images.
- Section *6 Viewbox and Viewing Conditions Test on page 23*.
- Section *7 AOP Mode and SNR Check on page 24*. Checks for correct operation of AOP mode.

Note:

GE recommends that Standard (STD) and Dose (DOSE) mode be used for routine mammography.

Contrast (CNT) mode of the Senographe DS delivers more dose than Standard (STD) and Dose (DOSE) modes.

GE recommends that Contrast (CNT) mode be used only after consultation with an interpreting physician or radiologist.

- Section *8 Visual Checklist on page 26*.
- Section *9 Repeat Analysis Check on page 27*. Analysis of the number and cause of repeated mammograms. Depending on your Senographe DS version, the method used may be manual or automated.
- Section *10 Compression Force Test on page 38*. Checks for the correct level of compression force.
- Section *11 Printer on page 39* addresses the QC testing of the printer used with the Senographe DS. To ensure optimal quality of the film printer output, follow the QC program developed by the manufacturer of the device. Refer to the Printer Operator's Manual or ancillary documentation provided by the manufacturer of the printer.

  If the printer is used with a film processor incorporating wet chemistry processing, refer to the Printer Operator's Manual or ancillary documentation provided by the manufacturer of the printer. If such documentation is not available, refer to Chapter 3 *Guidance* section *1 Wet Chemistry Film Processing on page 101*.
- Section *12 Test Results Record Forms on page 41* provides charts for use in recording the results of the various checks. It is recommended that you use these chart pages to make copies for the results.

For further analysis, data generated on the Acquisition Workstation (AWS) for Flat Field, CNR, MTF, AOP and SNR tests can be exported as text files to either a floppy disk or to a CD-R. The available option will be indicated by the pop-up described below.

To export the QC data files:

- From the Browser, click the QAP button, then select *Extract Data*.
- A pop-up is displayed instructing you to insert either a floppy disk or a CD-R, the choice of medium depending on the drive installed in the workstation. Insert the appropriate medium in the AWS drive and click OK.

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This action saves the data generated since the last data export.

Exported files can be easily opened on a computer using a word processing application. They contain the data displayed on the screen at the end of each test.

Note:

Files exported once cannot be exported a second time.

2 QC Intervals

The Quality Assurance Procedures described here must be performed at least as frequently as the intervals specified in the test descriptions and summarized below.

Minimum Frequency	Procedure	Section
Daily	Monitor Cleaning	*3*
Weekly	Flat Field Test	*4-1*
	Phantom Image Quality Tests	*4-2*
	CNR and MTF Measurement	*5*
	Viewbox and Viewing Conditions Test	*6*
Monthly	AOP Mode and SNR Check	*7*
	Visual Checklist	*8*
Quarterly	Repeat Analysis Check	*9*
Semi-annually	Compression Force Test	*10*

For the frequency of QC tests to be performed on the film printer, refer to the Printer Operator's Manual or ancillary documentation provided by the manufacturer of the printer.

Refer to Chapter 3 *Guidance* for additional information regarding application of the QC Tests.

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3 Monitor Cleaning

- Frequency:
  Daily or on days when clinical image acquisitions are planned.
- Objective:
  To ensure good image review conditions by keeping the monitor screen free of dust, finger prints, and other marks.
- Equipment required:
  Microfiber cloth.
  If necessary, the cloth may be moistened with either water or ethyl alcohol (up to 96%).

! Notice:

Do not use isopropyl (“rubbing”) alcohol.

Do not use cleaning agents which attack the surface, such as petroleum (mineral) spirits.

The front panel is extremely sensitive to mechanical damage. Avoid all scratches, knocks, etc.

Do not apply the cleaning liquid directly to the monitor housing or screen.

Do not allow the cleaning liquid to enter the monitor housing; be sure to dampen the cloth sparingly.

- Procedure:
  1. Check the screen to verify that it is free from dust, finger prints, and other marks.
  2. If the front panel is dirty, clean it using a microfiber cloth. If necessary, moisten the cloth with either water or ethyl alcohol (up to 96%). Remove any drops of cleaning liquid immediately; extended contact may discolor the surface. If it is necessary to clean the housing, use the microfiber cloth, moistened if necessary with water or ethyl alcohol.
  3. Check the screen to verify that it is free from dust, finger prints, and other marks.
  4. Record completion of the check on *Chart 1. Daily and Weekly Tests on page 41*.
- Action Limit:
  The screen must be free from dust, finger prints, and other marks.
- Use of Test Results:
  If these results are not obtained, the source of the problem must be identified, and corrective action taken, before any further mammographic images are acquired using the Senographe DS FFDM system that failed. Refer to Chapter 3 *Guidance* section *8-2 Monitor Cleaning on page 105*.

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4 Flat Field and Phantom IQ Tests

4-1 Flat Field Test

Note:

The Flat Field tests must be run before the Phantom IQ tests and the CNR and MTF Measurement test.

- Frequency:

  Weekly.
- Objective:

  Five tests are carried out when the Flat Field test is selected. They check brightness non-uniformity, high frequency modulation (HFM), SNR non-uniformity, bad ROI, and bad pixel verification.
- Equipment required:

  Flat field test object. This is an X-ray attenuator composed of 25 mm acrylic (PMMA) covering the entire image receptor (190 mm x 230 mm).

! Notice:

To avoid false results, the acrylic must be clean and free from imperfections.

Note:

To allow for temperature stabilization of the detector, the system must be powered on for at least 10 minutes before performing any measurements related to detector image quality. If any test is not passed after allowing a 10-minute warm-up period, see Chapter 3 *Guidance* section *2 Flat Field Test on page 101* .

- Procedure:
  1. Click on the QAP button in the right column of the Browser window. A list of tests is displayed. Select the Flat Field test.
  2. Use the light field to ensure that the collimators are set for the largest field of view.
  3. Set the tube arm angle to zero degrees.
  4. Follow the on-screen instructions. You are instructed to:
     - Remove the compression paddle and remove the Bucky.
     - Place the test object in the field of view, directly on the image receptor.
     - The following parameters are selected automatically: large focal spot, Mo/Mo track/filter, 26 kV, 200 mAs.
     - Make two exposures.
  5. After the second image has been captured, the results of the test are displayed. If all of the tests are passed, note in *Chart 1. Daily and Weekly Tests on page 41* that the test was completed and record the results in *Chart 2. Image Quality and MTF Measurement Test Record (1/3) on page 42*.

Note:

The display of test results will indicate if the system finds a test failure during the procedure (Brightness non-uniformity test failed, HFM test failed, SNR non-uniformity test failed, Bad ROI, or Bad Pixel Verification test failed).

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6. If all tests are not passed, check the test conditions and repeat the test.
   - Ensure that the detector has been allowed to warm up for at least 10 minutes before acquiring the test images.
   - Ensure that the compression paddle and Bucky have been removed.
   - Ensure that no object but the Flat Field Test Object is in the field.
   - Ensure that the collimator is open to the largest field size.
   - Ensure that the tube arm angle is at zero degrees.
   - Ensure that the Flat Field Test Object is clean and free from scratches or other imperfections:
   - Clean or replace the test object as necessary.

   If there is a scratch or defect near an edge of the test object, attempt to orient the test object so that the imperfection is outside the field of view of the image receptor. After re-orienting the test object, ensure that it still fills the field of view of the image receptor.
   - Ensure that the surface of the image receptor is clean.
   - Ensure that the Flat Field Test Object fully covers the field of view of the image receptor.

- Action Limit:

  Each of the Flat Field tests must be passed.
- Use of Test Results

  If the system fails the test, the source of the problem must be identified, and corrective action taken, before any further mammographic images are acquired using the Senographe DS system that failed. Refer to Chapter 3 *Guidance* section *2 Flat Field Test on page 101*.

4-2 Phantom IQ on AWS and Printer Test

- Frequency:

  Weekly.

  This test must be run only after successful completion of the Flat Field test.

  The Phantom Image Quality Test of the printer must be run only after successful completion of the daily QC test for the printer.
- Objective:

  The test is designed to ensure adequate and consistent quality of images acquired by the detector and displayed on the AWS monitor and the printer.

Note:

The image needed for this test is acquired using the manual mode of the Senographe DS. The test is intended to check the consistency of the detector and display sub-systems independently of the functioning of the AOP automatic exposure control system. Operation of AOP is checked in section *7 AOP Mode and SNR Check on page 24*. At the user's discretion, **additional** images may be acquired and analyzed using one or more of the AOP modes and the applicable procedures given below. While such additional images may be of interest to some users, they are not required as part of these QC tests and no Action Limits are provided.

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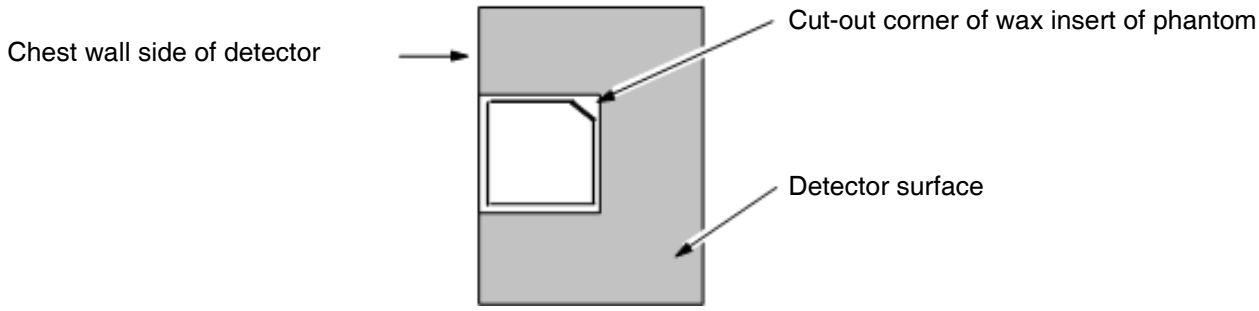
- Equipment required:
  Mammographic Quality Control phantom. Refer to Chapter 3 *Guidance* section *3-1 Quality Control Phantom on page 102*.

Note:
To avoid false results, the phantom must be clean and free from imperfections.

Note:
To allow for temperature stabilization of the detector, the system must be powered on for at least 10 minutes before performing any measurements related to detector image quality. If any test is not passed after allowing a 10-minute warm-up period, see Chapter 3 *Guidance* section *3-3 Failure of Phantom Image Quality Test on page 102*.

4-2-1 Image Acquisition

- Procedure:
  Run the normal Medical Application; follow the sequence of instructions below.
  1. Install the grid if it is not already in place.
  2. Position the phantom on the breast support surface in the field of view of the image receptor. One edge of the phantom must be flush with the chest wall edge of the breast support surface. When viewed from the patient's position, i.e., facing the mammography unit, the cut-out corner of the wax insert of the phantom must be opposite to the chest wall and toward the left side of the detector, as indicated below. Select the 9 x 9 cm X-ray field size and use the light localizer to center the phantom laterally.



  3. Reset the collimator to the maximum field of view.
  4. Install the full-size compression paddle and apply about 5 daN of compression force to the phantom.
  5. Select the following parameters: large focal spot, Rh/Rh track/filter, 29 kV, 56 mAs.
  6. On the AWS select a new patient, e.g., *Phantom Image*, under Medical Applications.
  7. On the Control Console select *Left* breast laterality.
  8. Make an exposure. Check that the collimator blades are not visible on the image. If collimator blades are visible, refer to Chapter 3 *Guidance* section *3-4 Appearance of Collimator Blades in Image on page 102*.

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4-2-2 Phantom IQ test on AWS

- Procedure:
  1. Observe the image and provide a score for each target in the phantom image on the AWS screen. Scores must include deduction for artifacts. For a recommendation on a method for determining the score, including artifact deduction, see Chapter 3 *Guidance* section *3-2 Scoring the Phantom Image on page 102*. If objects are not easy to see, make sure that the phantom image is positioned for optimal viewing, and use the Zoom, Rotation, Magnifying Glass, Brightness, and Contrast controls as necessary so that the most accurate score can be obtained.
  2. Record the display settings and results in *Chart 2. Image Quality and MTF Measurement Test Record (1/3) on page 42*.
- Action Limit

  If the score for fibers is less than 4, the score for masses is less than 3, or the score for calcifications is less than 3, the test has failed.
- Use of Test Results:

  If the system fails the test, the source of the problem must be identified, and corrective action taken, before any further mammographic images are acquired using the Senographe DS system that failed. See Chapter 3 *Guidance* section *3-3 Failure of Phantom Image Quality Test on page 102*.

4-2-3 Phantom IQ Test on the Printer

- Procedure:
  1. Before testing the printer, first do the daily QC test for the printer.
  2. Push the **Processed** *Phantom Image* to the Printer.
  3. Observe the printed image of the phantom and provide a score for each target in the same way as described above. Scores must include deduction for artifacts. For a recommendation on a method for determining the score, including artifact deduction, see Chapter 3 *Guidance* section *3-2 Scoring the Phantom Image on page 102*.
  4. Record the results in *Chart 2. Image Quality and MTF Measurement Test Record (1/3) on page 42*.
- Action Limit:

  If the score for fibers is less than 4, the score for masses is less than 3, or the score for calcifications is less than 3, the test has failed.
- Use of Test Results:

  If the system fails the test, the source of the problem must be identified, and corrective action taken, before any further mammographic images are reviewed or interpreted using the printer. See Chapter 3 *Guidance* section *3-5 Failure of Phantom Image Quality Test for Printer on page 102*.

4-2-4 Completion of Phantom Image Quality Test

- Recording of completion of tests

  After completing all elements of the Phantom Image Quality Test, record the completion of the test in *Chart 1. Daily and Weekly Tests on page 41*.

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The applicable MQSA Quality Mammography Standard is:

900.12(e)(2)

Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

(iii) The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA in accordance with Sec. 900.3(d) or Sec. 900.4(a)(8).

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5 CNR and MTF Measurement

- Frequency:

  Weekly.

  The measurement must be made only after successful completion of the Flat Field Test (section *4-1 Flat Field Test on page 16*).
- Objective:

  The test is designed to check the consistency of the contrast to noise ratio (CNR) and to ensure that contrast is adequate over the 0-5 lp/mm spatial frequency range by obtaining an estimate of the MTF (Modulation Transfer Function) values at 2 and 4 lp/mm.

  CNR measurement is done in two steps:
  - Establishment of a baseline operating level, CNR_{ol} (CNR Operating Level).
  - Comparison of CNR value to this operating level.

  Note:

  The phantom image quality test for screen-film imaging systems as described in the MQSA Quality Mammography Standards includes a test for the consistency of image contrast as represented by the density difference (DD) between the image of an added test object, e.g., a 4 mm thick acrylic disk, and the background density of the phantom. In digital imaging the relative level of a signal or contrast to the image noise is the more relevant measure of image quality. Hence, the measure of consistency of Contrast-to-Noise Ratio (CNR) is introduced as a replacement for the measure of consistency of DD.
- Equipment required:

  IQST device shipped with the Senographe DS system.
  To avoid false results, the device must be clean and free from scratches.

  Note:

  To allow for temperature stabilization of the detector, the system must be powered on for at least 10 minutes before performing any measurements related to detector image quality. If any test is not passed after allowing a 10-minute warm-up period, see the Chapter 3 *Guidance* section *4 CNR and MTF Measurement on page 103*.
- Establishing a baseline operating level for the CNR measurement, CNR_{ol}:

  It is first necessary to establish an operating level for the Contrast-to-Noise Ratio (CNR) measurement, CNR_{ol}.

  To do so, on each of five consecutive days, begin with the Flat Field test (section *4-1 Flat Field Test on page 16*), then follow steps 1 through 8 of the procedure below in order to acquire a new image. The CNR will be automatically calculated as well as the average of the first five CNR values. The average is used as the operating level. Record the daily values and the resulting operating level in *Chart 2. Image Quality and MTF Measurement Test Record (2/3) on page 43*. The subsequent weekly measurements are to be compared to this operating level.
- Changes to the baseline operating level for the CNR measurement, CNR_{ol}:

  Under certain conditions it will be necessary to re-establish the CNR_{ol}. These include, but are not limited to:
  - Replacement of the X-ray tube.
  - Replacement of the Rh X-ray beam filter.
  - Replacement of the IQST device.

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- Replacement of the anti-scatter grid.
- Replacement of the detector.
- Re-calibration of detector gain.

Following any of these events it is necessary to again average the CNR values measured on **five consecutive days** and use the average as the new CNR_{ol}. To initiate the establishment of a new CNR_{ol}, use the reset button in the *Results* pop-up window.

- Procedure:
  1. Click on the QAP button on the right column of the Browser window. A list of tests is displayed. Select the CNR and MTF Measurement test.
  2. Enter or verify the reference of the IQST device (Serial Number or SN, written on the side of the device) on the AWS screen, then click *Start*.

Note:
If the device reference entered is different from the previous one, you will be asked if you want to restart the calibration process with this new reference.

  3. Install the Bucky on the digital detector if it is not already installed.
  4. Remove the compression paddle.
  5. Position the IQST device on top of the Bucky.
  6. The following parameters are selected automatically: Rh/Rh/30kV/56mAs.
  7. Perform one exposure.
  8. After the image has been captured, the results of the tests are displayed:
     - The values of MTF at 2 lp/mm and MTF at 4 lp/mm.
     - The value of the change in CNR, computed as follows:

$$\text{Change in CNR} = |CNR - CNR_{ol}| / CNR_{ol}$$

     - CNR_{ol} = the CNR Operating Level as described above.
  9. If all the tests are passed, record the results in *Chart 2. Image Quality and MTF Measurement Test Record (3/3) on page 44*.

- Action Limit:

The system passes the MTF Measurement test if the following conditions are met:

MTF Parallel at 2lp/mm > 58%

MTF Parallel at 4lp/mm > 25%

MTF Perpendicular at 2lp/mm > 58%

MTF Perpendicular at 4lp/mm > 25%

For each condition that is met, the *Status* will be *Pass*.

The system passes the CNR Measurement test if the change in CNR does not exceed 0.2. If this condition is met, the *Status* will be *Pass*.

- Use of Test Results:

If the system fails either of these tests,the source of the problem must be identified, and corrective action taken, before any further mammographic images are acquired using the Senographe DS system that failed. See Chapter 3 *Guidance* sections *4-1 Failure of MTF Measurement Test on page 103* and *4-2 Failure of Change in CNR Test on page 103*.

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6 Viewbox and Viewing Conditions Test

- Frequency:
  Weekly.
- Objective:
  To ensure good image review conditions by keeping the viewboxes free of dust, finger prints, and other marks and the viewing conditions optimized.
- Procedure:
  1. This test is not specific to digital mammographic systems. Follow accepted mammographic QC procedures to perform this test. See Chapter 3 *Guidance* section *8-1 Viewboxes and Viewing Conditions on page 105*.
  2. Indicate completion of the test in *Chart 1. Daily and Weekly Tests on page 41*.
- Action Limit:
  The viewboxes must be free from dust, finger prints, and other marks. Viewing conditions must meet accepted standards for mammographic image review.
- Use of Test Results:
  If these results are not obtained, the source of the problem must be identified, and corrective action taken, before any further mammographic images are reviewed or interpreted using the viewboxes.

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7 AOP Mode and SNR Check

- Frequency:
  Monthly.
- Objective:
  The test is designed to check the following aspects of system operation:
  - Correct choice of parameters in AOP (Automatic Optimization of Parameters) mode.
  - Correct level of SNR (Signal-to-Noise Ratio) in the image.

Note:
GE recommends that Standard (STD) and Dose (DOSE) mode be used for routine mammography.
Contrast (CNT) mode of the Senographe DS delivers more dose than Standard (STD) and Dose (DOSE) modes.
GE recommends that Contrast (CNT) mode be used only after consultation with an interpreting physician or radiologist.

- Equipment required:
  Set of acrylic plates (PMMA) allowing thicknesses of 25 ± 0.1 mm, 50 ± 0.1 mm and 60 ± 0.1 mm.

! Notice:
To avoid false results, the plates must be clean and free from scratches.

Note:
To allow for temperature stabilization of the detector, the system must be powered on for at least 10 minutes before performing any measurements related to detector image quality. If any test is not passed after allowing a 10-minute warm-up period, see Chapter 3 *Guidance* section *5 AOP Mode and SNR Check on page 103*.

- Procedure:
  1. Click on the QAP button in the right column of the Browser window. A list of tests is displayed. Select the AOP and SNR Check test.
  2. The following procedure must be carried out for each of the three thicknesses of acrylic in the field of view, i.e. 25, 50 and 60 mm, starting with the 25 mm thickness:
     - Select the 25 mm button.
     - Place the acrylic plates so that they lie flat on the breast support surface of the Bucky.
     - Position the plates with the longest side aligned with the chestwall edge of the Bucky.
     - Center the plates left-to-right.
     - Apply a compression force of 5 daN to the plates.

Note:
For precision and ease of selection, the maximum compression force limit can be set to 5 daN using the Medical/Force menu on the X-ray console menu. If this is done, return the maximum to the clinically used value following completion of the test. For information on setting the maximum compression force see Chapter 3 *Guidance* section *5 AOP Mode and SNR Check on page 103*.

- AOP STD mode is selected automatically.
- Select *Left* breast laterality and take an exposure.
- After the image has been captured, the results are displayed (exposure parameters used as well as SNR).

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- Record the results in *Chart 3. AOP Mode and SNR Check Records on page 45*. See Chapter *3 Guidance* section *5 AOP Mode and SNR Check on page 103* regarding a method to record these results.
- Repeat these steps for the 50 and 60 mm thicknesses.

- Action Limit:
  - If, at the end of the results, ***AOP B*** is displayed, the AOP Mode test is successful if the exposure parameters are in accord with the values specified in *Table 1*:

Table 1 Action Limit when *AOP B* is displayed

Acrylic Thickness (mm)	Exposure ParametersFor AOP STD mode only		
	Track/Filter	mAs	kV
25	Mo/Mo	20-60	26
50	Rh/Rh	40-90	29
60	Rh/Rh	60-120	30 or 31

If ***AOP B*** is not displayed at the end of the results, the AOP Mode test is successful if the exposure parameters are in accord with the values specified in *Table 2*:

Table 2 Action Limit when *AOP B* is not displayed

		Exposure Parameters For AOP STD mode only		
AWS version (*)	**Acrylic Thickness (mm)**	**Track/filter**	**mAs**	**kV**
any	25	Mo/Mo	20-60	26
any	50	Rh/Rh	40-90	29
V:32.10 and lower	60	Rh/Rh	45-95	31
V:43.0 and higher	60	Rh/Rh	45-95	30 or 31

(*) The software version is displayed in the title bar of the Browser in the form AWS-V:X.Y, for example, as AWS-V:32.10 or AWS-V:43.0.

Note:

For AWS software version equal to V43.0 or higher:
Either of two values of kVp, 30 or 31, may be selected by the AOP algorithm for the 60 mm acrylic thickness. This is normal operation. It is also normal operation that the mAs used with 30 kVp will be greater than the value used with 31 kVp. It is only necessary that the mAs remain within the range given in the previous table.

The value of SNR must exceed 50.

- Use of Test Results:

  If the system fails the test, the source of the problem must be identified, and corrective action taken, before any further mammographic images are acquired using the Senographe DS FFDM system that failed, See Chapter *3 Guidance* section *5 AOP Mode and SNR Check on page 103*.

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8 Visual Checklist

- Frequency:
  Monthly and after any service or maintenance on the mammographic X-ray system.
- Objective:
  To assure that mammographic X-ray system indicator lights, displays, and mechanical locks and detents are working properly and that the system is mechanically stable.
- Equipment required:
  Visual checklist *Chart 4. Visual Checklist Record on page 46*.
- Procedure:
  1. Review each item on the visual checklist and indicate its status.
  2. Date and initial the checklist where indicated.
  3. Note on *Chart 5. Record of Checks on page 47* the completion of the Visual Checklist.
- Action Limit:
  Each of the items listed in the Visual Checklist must pass or receive a check mark. Items missing from the room must be replaced immediately.
- Use of Test Results:
  If an item does not pass the visual check, the source of the problem must be identified and corrective actions shall be taken before any further mammographic images are acquired using the Senographe DS FFDM system that failed.
  See Chapter 3 *Guidance* section *8 Visual, Monitor, and Filming Checks on page 105*.

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9 Repeat Analysis Check

The applicable MQSA Quality Mammography Standard is:

900.12(e)(3)(ii)
Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

(ii) Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

- Depending on the version of your Senographe DS, the method used may be manual or automated:

Method	Senographe DS version	Description
Manual	All versions	Data are recorded on a paper chart. Repeat rates are calculated manually, and the results recorded on a paper chart.
Automated	Versions with Repeat and Reject Analysis. Verify presence of *RRA* button after selecting QAP from the browser.	Each image must be qualified during the examination as *Accepted*, *Rejected*, or *Repeated*. See Chapter 3 *Guidance* section *6-2 Automated Method on page 104*. Repeat and reject rates are calculated automatically.

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9-1 Repeat Analysis - Manual Method

- Frequency:
  Quarterly. For the repeat rates to be meaningful, an analysis period that yields a patient volume of at least 250 patients or 1,000 exposures is needed.
- Objective:
  To determine the number and cause of repeated digital mammograms. Analysis of these data can help identify ways to improve system efficiency and reduce digital image retakes and patient exposure.
- Equipment required:
  - Records of all exposures made during the period being analyzed.
  - Repeat exposure record sheet(s) *Chart 6. Repeat Exposure Record Sheet - Manual Method on page 48*.
  - Repeat analysis data sheet *Chart 7. Repeat Exposure Analysis - Manual Method on page 49*.
- Procedure:
  1. Identify all exposures which had to be repeated. Record each one on *Chart 6. Repeat Exposure Record Sheet - Manual Method on page 48*, entering the Study Number, cause of repeated exposure, date, etc.
  2. At the end of each analysis period, use the repeat exposure analysis form *Chart 7. Repeat Exposure Analysis - Manual Method on page 49* to summarize the number of repeats in each category and record your analysis of results.
     - Estimate the total number of exposures taken during the analysis period. See Chapter 3 *Guidance* section *6 Repeat Analysis Check on page 104*.
     - Calculate the overall repeat rate as the total of repeated exposures (R) divided by the total number of exposures (T) during the analysis period, multiplied by 100%.
     - Determine the percentage of repeats in each category by dividing the number of repeats in the category by the total number of repeated exposures (R) from all categories.
  3. Record completion of the Repeat Analysis Check on *Chart 5. Record of Checks on page 47*.
- Action Limit:
  The total repeat rate or reject rate must not change by more than 2.0% of the total exposures included in the analysis from the rate determined for the previous analysis period.
- Use of Test Results:
  If the total repeat rate or reject rate changes from the rate determined for the previous analysis period by more than 2.0% of the total exposures included in the analysis, the source of the problem must be identified, and corrective action taken, within 30 days of the test date. Any corrective actions taken must be recorded, and an assessment must be made of their effectiveness.

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9-2 Repeat Analysis - Automated Method

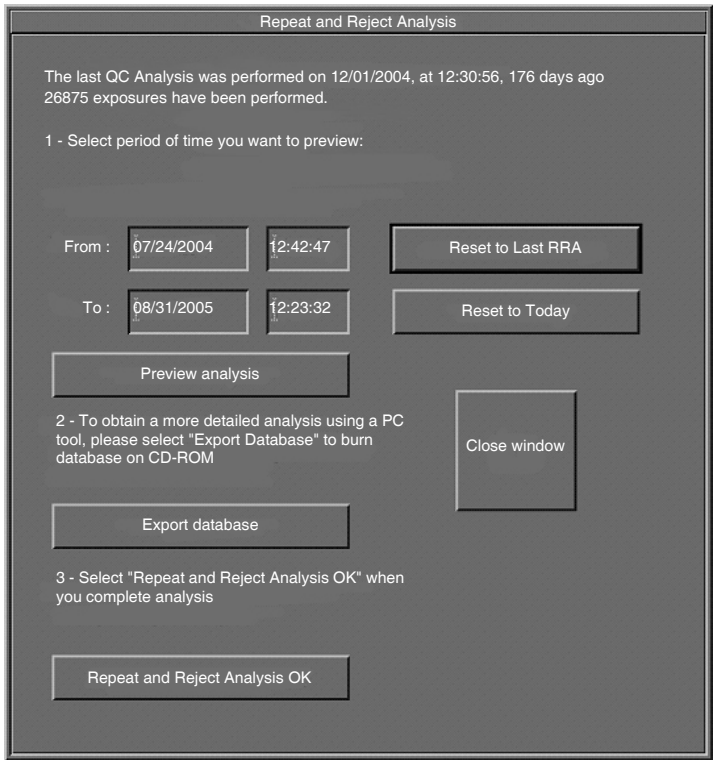
Note:

The procedure described here performs Repeat and Reject Exposure analysis using the Senographe DS Control Station computer. It is also possible to export the recorded data and perform the analysis on another computer (PC-compatible) using the PC Tool. To export the data on CD, click the *Export database* button in the *Repeat and Reject Analysis* window described below. Use of the PC Tool to analyze the data is described in section *9-4 Repeat Analysis - PC Tool on page 33*.

- Frequency:

  Quarterly. For the repeat rates to be meaningful, an analysis period that yields a patient volume of at least 250 patients or 1,000 exposures is needed.
- Objective:

  To determine the number and cause of repeated and rejected digital mammograms.
  Analysis of these data can help to identify ways to improve system efficiency and reduce digital image retakes and patient exposure to radiation.
- Equipment required:
  - Repeat and Reject analysis data sheet *Chart 8. Repeat and Reject Exposure Analysis - Automated Method on page 50*.
- Procedure:
  - Ensure that all exposures made during the analysis period have been qualified.
  - Select the QAP icon in the browser, then click the *RRA* button to display the *Repeat and Reject Analysis* window.


Repeat and Reject Analysis
The last QC Analysis was performed on 12/01/2004, at 12:30:56, 176 days ago
26875 exposures have been performed.
1 - Select period of time you want to preview:
From :
07/24/2004
12:42:47
Reset to Last RRA
To :
08/31/2005
12:23:32
Reset to Today
Preview analysis
2 - To obtain a more detailed analysis using a PC tool, please select "Export Database" to burn database on CD-ROM
Close window
Export database
3 - Select "Repeat and Reject Analysis OK" when you complete analysis
Repeat and Reject Analysis OK

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- In the *Repeat and Reject Analysis* window, select *From* and *To* dates for the analysis, then click *Preview analysis* to display the *Repeat Reject Exposures Analysis* table in the format shown in the example below.

The table summarizes all exposures made during the chosen period, and gives the percentages for Repeated and Rejected exposures, together with their respective causes.

! Notice:

Data are ignored from any technologist whose name has been entered with two or more consecutive space characters. Check that the names of all technologists are entered correctly and make any corrections for future analyses.

Repeat Reject Exposures Analysis

Cause	Number of Repeats	Percentage of Repeats	Number of Rejects	Percentage of Rejects
Positioning	7	27%	0	0%
Patient Motion	8	31%	0	0%
Poor Compression	4	15%	0	0%
Improper Detector Exposure	0	0%	1	3%
X-Ray Equipment Failure	0	0%	0	0%
Equipment Artifacts	1	4%	0	0%
Blank Image	0	0%	0	0%
Clinical Artifacts	6	23%	0	0%
Incorrect View Marker	0	0%	0	0%
QC, Acceptance Tests, Calibration	0	0%	24	63%
Interventional Image (e.g., wire loc.)	0	0%	13	34%
Other	0	0%	0	0%

Total Repeats + Rejects	64
Total Repeats	26
Total Rejects	38
Non-Clinical Repeats+Rejects	37
Total number of exposures	1430
Total Repeat+Reject rate	4.5%
Total Repeat rate	1.8%
Clinical Repeat rate	1.9%

Close this window

Note:

The MQSA does not specify the statistics to be used in calculating a repeat or reject rate.

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Three rates are provided by this analysis tool. They are calculated as follows:

$$\text{Total Repeat+Reject rate (\%)} = \frac{100 \times \textit{Total Repeats + Rejects}}{\textit{Total number of exposures}}$$

$$\text{Total Repeat rate (\%)} = \frac{100 \times \textit{Total Repeats}}{\textit{Total number of exposures}}$$

$$\text{Clinical Repeat rate (\%)} = \frac{100 \times \textit{Total Repeats}}{\textit{Total number of exposures - Non-Clinical Repeats+Rejects}}$$

- *Total Repeats + Rejects* is the sum of all images qualified as either *Repeated* or *Rejected* in the analysis period.
- *Total Repeats* is the sum of all images qualified as *Repeated* in the analysis period.
- *Total number of exposures* is the count of images acquired in the analysis period.
- *Non-Clinical Repeats+Rejects* is the sum of *Repeats* plus *Rejects* for the causes *QC, Acceptance Tests, Calibration* and *Interventional Image (e.g., wire loc.)* in the analysis period.

It is the responsibility of the facility to decide on the repeat or reject rate to monitor as part of its quality assurance plan. The facility may choose one of those provided in the automated analysis, or calculate rates by other means using the statistics accumulated by the analysis tool. The facility must identify the chosen method in its QC log.

- Action Limit:

  The total repeat rate or reject rate must not change by more than 2.0% of the total exposures included in the analysis from the rate determined for the previous analysis period.
- Use of Test Results:

  If the total repeat rate or reject rate changes from the rate determined for the previous analysis period by more than 2.0% of the total exposures included in the analysis, the source of the problem must be identified, and corrective action taken, within 30 days of the test date. Any corrective actions taken must be recorded, and an assessment must be made of their effectiveness.

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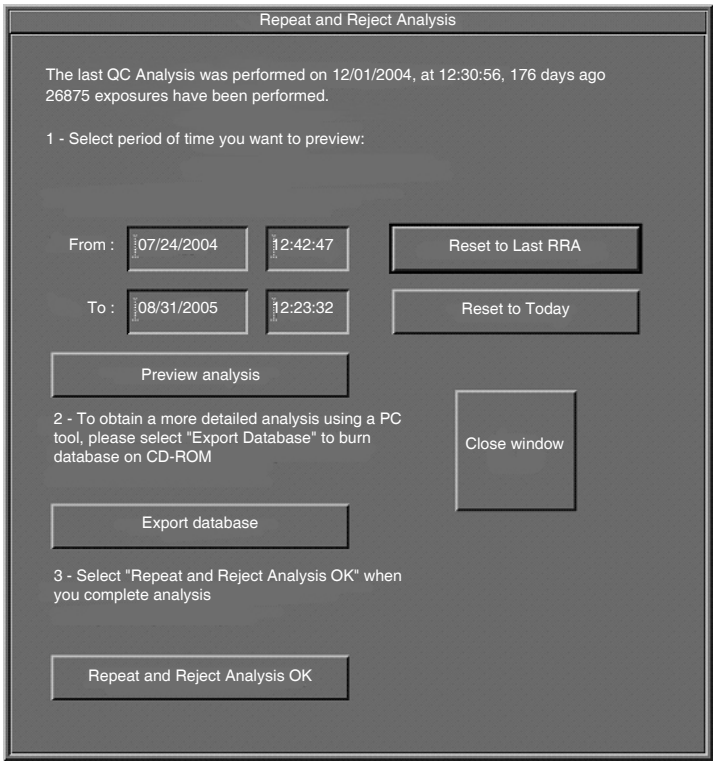
9-3 Repeat Analysis - Database backup

- Frequency:
  After each repeat analysis, at least quarterly or more often if repeat analysis is done more frequently. See Chapter 3 *Guidance* section *6-3 Record of loss of data on page 104*.
- Objective:
  To backup the repeat analysis database and limit the loss of data due to a failure of system hardware.
- Equipment required:
  A blank CD.
- Procedure:
  - Select the QAP icon in the browser, then click the *RRA* button to display the *Repeat and Reject Analysis* window.
  - Click the *Export database* button in the *Repeat and Reject Analysis* window.


Repeat and Reject Analysis
The last QC Analysis was performed on 12/01/2004, at 12:30:56, 176 days ago
26875 exposures have been performed.
1 - Select period of time you want to preview:
From :
07/24/2004
12:42:47
Reset to Last RRA
To :
08/31/2005
12:23:32
Reset to Today
Preview analysis
2 - To obtain a more detailed analysis using a PC tool, please select "Export Database" to burn database on CD-ROM
Close window
Export database
3 - Select "Repeat and Reject Analysis OK" when you complete analysis
Repeat and Reject Analysis OK

  - A pop-up is displayed, asking you to insert a blank CD in the CD writer. Insert a blank CD in the AWS CD writer and click *OK*.
  - This action saves the entire database to the CD. The database is also retained in the AWS computer.
  - A pop-up is displayed to confirm the completion of the CD burn.

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9-4 Repeat Analysis - PC Tool

Note:

This procedure provides an alternative to section *9-2 Repeat Analysis - Automated Method on page 29* as a means to perform the repeat analysis. It describes the use of the PC Tool to analyze on another computer (PC-compatible) the repeat and reject data exported to a CD.

- Frequency:

  Quarterly
- Objective:

  To perform the repeat analysis on another computer (PC-compatible), with supplementary statistics, e.g., results sorted by technologist or in order of decreasing frequency.
- Equipment required:
  - The CD that contains the repeat analysis database. Refer to section *9-3 Repeat Analysis - Database backup on page 32* for the procedure to export the database.
  - A PC-compatible computer
  - Windows operating system
  - Internet Explorer V6.0 or higher

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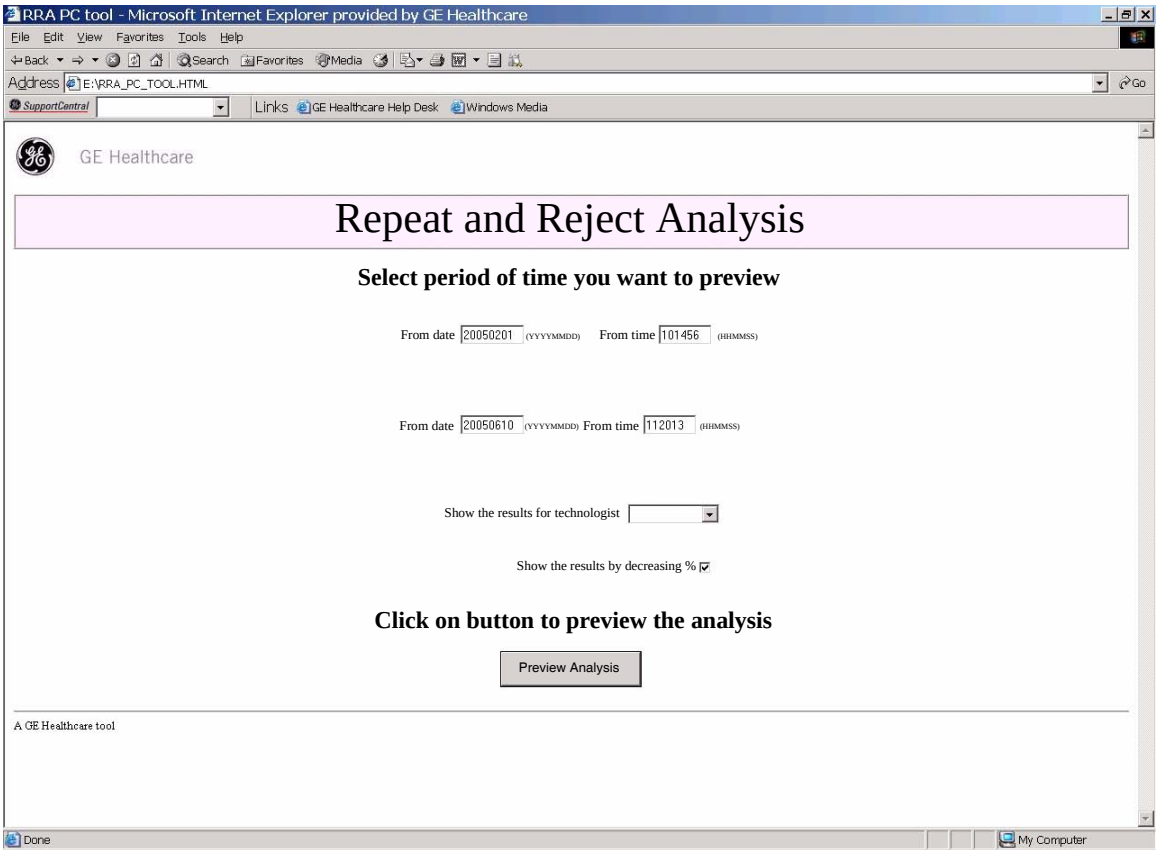
- Procedure:
  - Insert the CD in the CD drive of your computer.
  - Double click the CD icon to get the list of files on the CD.

Note:
If you copy the files onto your computer, make sure you put all the files in the same folder.

- Double click the RRA_PC_TOOL.html file to launch the application.
- Internet Explorer is automatically launched.
- The Selection page is displayed:


RRA PC tool - Microsoft Internet Explorer provided by GE Healthcare
File Edit View Favorites Tools Help
Address E:\RRA_PC_TOOL.HTML
Links GE Healthcare Help Desk Windows Media
GE Healthcare
Repeat and Reject Analysis
Select period of time you want to preview
From date 20050201 (YYYYMMDD) From time 101456 (HHMMSS)
From date 20050610 (YYYYMMDD) From time 112013 (HHMMSS)
Show the results for technologist
Show the results by decreasing %
Click on button to preview the analysis
Preview Analysis
A GE Healthcare tool
Done
My Computer

- Enter the period of time you would like to consider for the analysis.

Note:
By default, *From date* and *From time* are the date and time of the last repeat analysis performed on the Acquisition Workstation. *To date* and *To time* are the current date and time on the computer. Note that time is entered using a 24-hour clock.

- Select the technologist for whom you would like to get analysis results.

Note:
By default, the field is empty. Exposures by all the technologists will be taken into account for the analysis. Selection of a technologist is optional. If selected, results will be provided for the selected technologist, followed by the cumulative results for all technologists.

Note:
The list of technologists comes from the Acquisition Workstation. No modification of the list is possible in the PC Tool.

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- Click in the box *Show the results by decreasing %* if you want to display the causes ranked by decreasing percentage of occurrence.

Note:

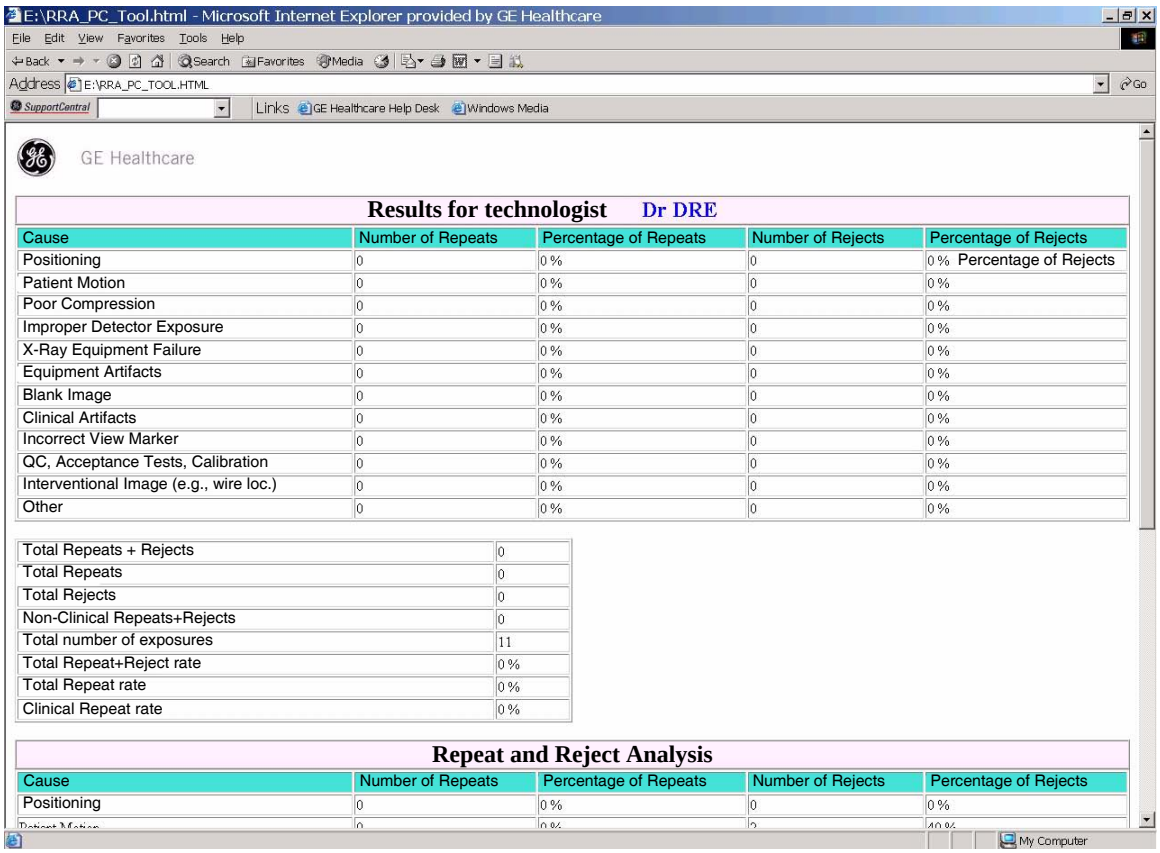
This is optional. Whether the box is selected or not, the causes are displayed.

- Click the *Preview Analysis* button to display the results of the requested repeat analysis.
- The Results page is displayed.

Note:

The repeat analysis data displayed with PC Tool are identical to the data obtained on the Acquisition Workstation for the same analysis period, apart from the display of results for a specific technologist that is available with the PC Tool only.

- If you selected a technologist, his/her results are first displayed.


E:\RRA_PC_Tool.html - Microsoft Internet Explorer provided by GE Healthcare
File Edit View Favorites Tools Help
Address E:\RRA_PC_TOOL.HTML
Links GE Healthcare Help Desk Windows Media
GE Healthcare
Results for technologist Dr DRE
Cause | Number of Repeats | Percentage of Repeats | Number of Rejects | Percentage of Rejects
Positioning | 0 | 0 % | 0 | 0 % Percentage of Rejects
Patient Motion | 0 | 0 % | 0 | 0 %
Poor Compression | 0 | 0 % | 0 | 0 %
Improper Detector Exposure | 0 | 0 % | 0 | 0 %
X-Ray Equipment Failure | 0 | 0 % | 0 | 0 %
Equipment Artifacts | 0 | 0 % | 0 | 0 %
Blank Image | 0 | 0 % | 0 | 0 %
Clinical Artifacts | 0 | 0 % | 0 | 0 %
Incorrect View Marker | 0 | 0 % | 0 | 0 %
QC, Acceptance Tests, Calibration | 0 | 0 % | 0 | 0 %
Interventional Image (e.g., wire loc.) | 0 | 0 % | 0 | 0 %
Other | 0 | 0 % | 0 | 0 %
Total Repeats + Rejects | 0
Total Repeats | 0
Total Rejects | 0
Non-Clinical Repeats+Rejects | 0
Total number of exposures | 11
Total Repeat+Reject rate | 0 %
Total Repeat rate | 0 %
Clinical Repeat rate | 0 %
Repeat and Reject Analysis
Cause | Number of Repeats | Percentage of Repeats | Number of Rejects | Percentage of Rejects
Positioning | 0 | 0 % | 0 | 0 %
My Computer

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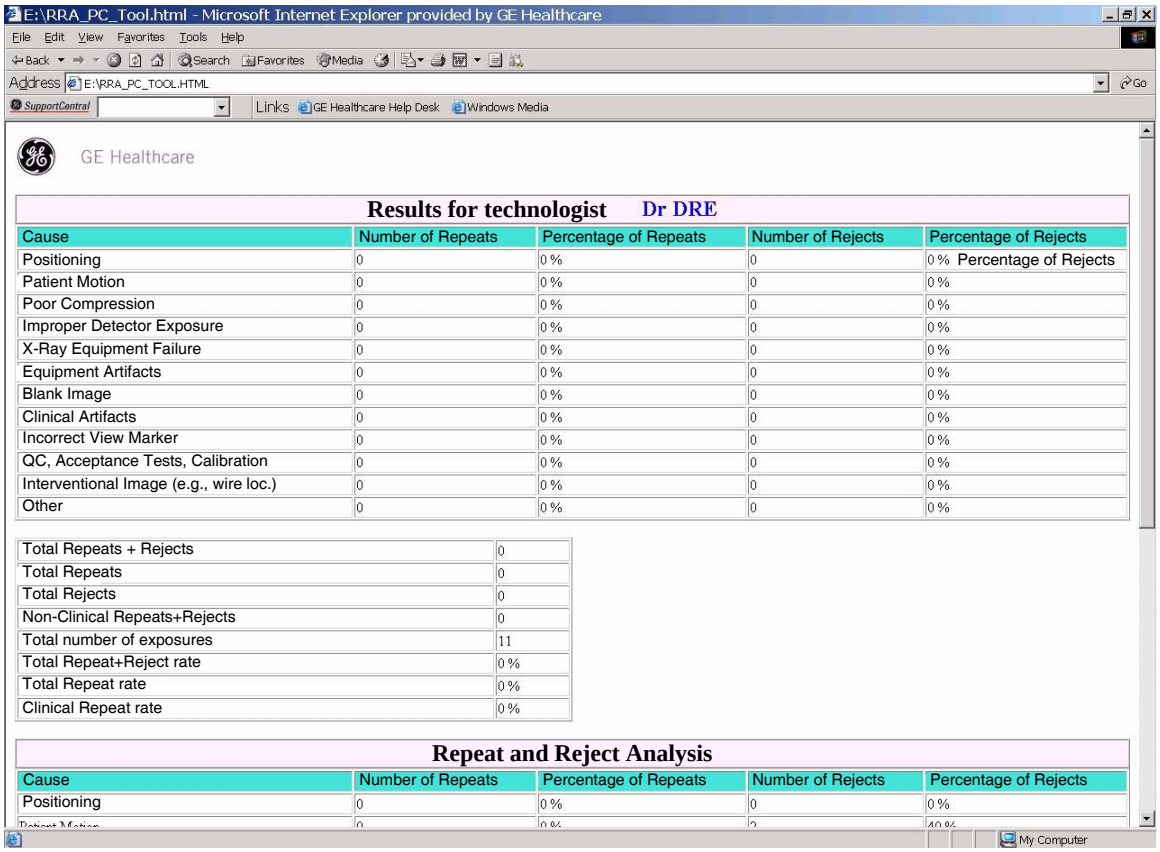
- The table containing the cumulative results of the analysis for all technologists is then displayed, regardless of the selection of the technologist (either all technologists or a specific one).



E:\RRA_PC_Tool.html - Microsoft Internet Explorer provided by GE Healthcare

File Edit View Favorites Tools Help

Back Search Favorites Media

Address E:\RRA_PC_TOOL.HTML Go

SupportCentral Links GE Healthcare Help Desk Windows Media

GE Healthcare

Results for technologist Dr DRE

Cause	Number of Repeats	Percentage of Repeats	Number of Rejects	Percentage of Rejects
Positioning	0	0 %	0	0 % Percentage of Rejects
Patient Motion	0	0 %	0	0 %
Poor Compression	0	0 %	0	0 %
Improper Detector Exposure	0	0 %	0	0 %
X-Ray Equipment Failure	0	0 %	0	0 %
Equipment Artifacts	0	0 %	0	0 %
Blank Image	0	0 %	0	0 %
Clinical Artifacts	0	0 %	0	0 %
Incorrect View Marker	0	0 %	0	0 %
QC, Acceptance Tests, Calibration	0	0 %	0	0 %
Interventional Image (e.g., wire loc.)	0	0 %	0	0 %
Other	0	0 %	0	0 %

Total Repeats + Rejects	0
Total Repeats	0
Total Rejects	0
Non-Clinical Repeats+Rejects	0
Total number of exposures	11
Total Repeat+Reject rate	0 %
Total Repeat rate	0 %
Clinical Repeat rate	0 %

Repeat and Reject Analysis

Cause	Number of Repeats	Percentage of Repeats	Number of Rejects	Percentage of Rejects
Positioning	0	0 %	0	0 %

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- A list of "other" causes is automatically displayed if any are found in the analysis.

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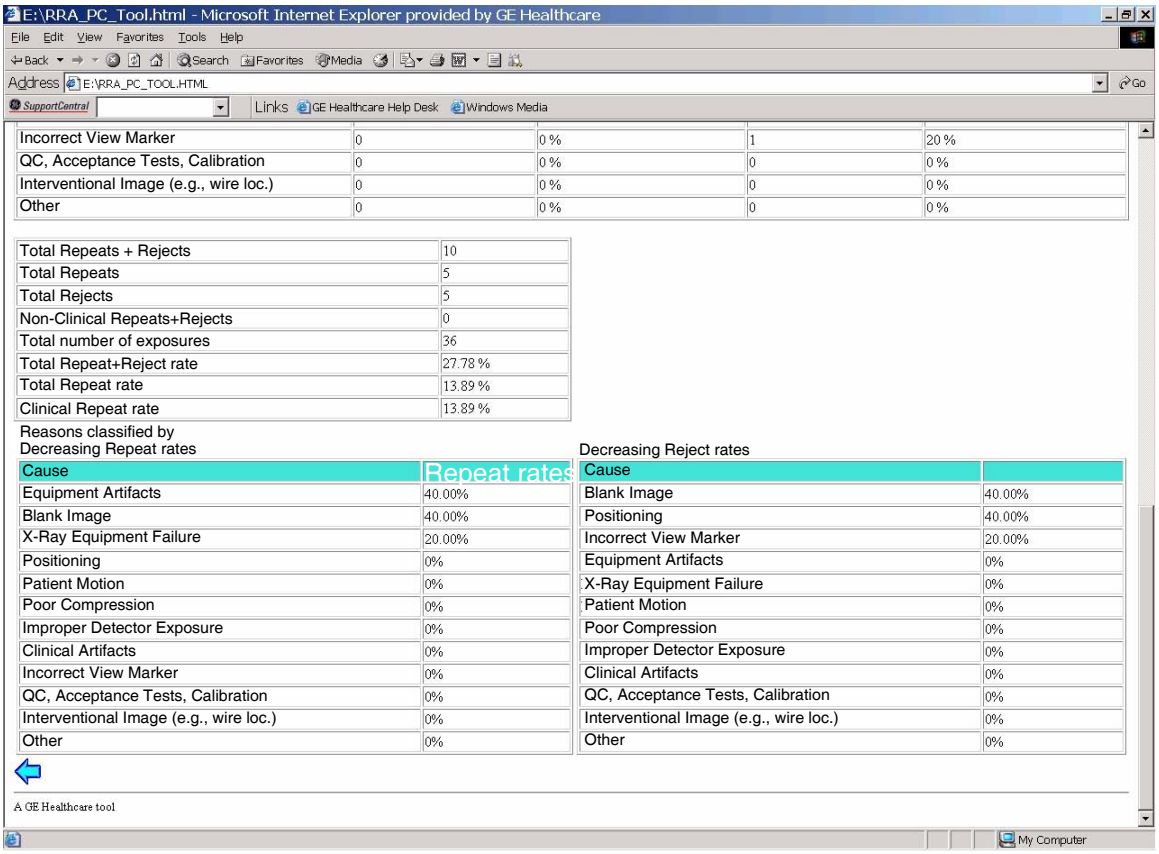
- If you requested the display of the causes by decreasing percentage of occurrence, then two tables are displayed: a table showing the list of repeat causes, ranked by decreasing percentage and a table showing the list of reject causes, also ranked by decreasing percentage. Each table shows the most frequent cause of repeat or reject on the first line.

Note:

If you did not select the decreasing percentage ranking, these tables are not displayed.


E:\RRA_PC_Tool.html - Microsoft Internet Explorer provided by GE Healthcare
File Edit View Favorites Tools Help
Address E:\RRA_PC_TOOL.HTML
Links GE Healthcare Help Desk Windows Media
Incorrect View Marker 0 0 % 1 20 %
QC, Acceptance Tests, Calibration 0 0 % 0 0 %
Interventional Image (e.g., wire loc.) 0 0 % 0 0 %
Other 0 0 % 0 0 %
Total Repeats + Rejects 10
Total Repeats 5
Total Rejects 5
Non-Clinical Repeats+Rejects 0
Total number of exposures 36
Total Repeat+Reject rate 27.78 %
Total Repeat rate 13.89 %
Clinical Repeat rate 13.89 %
Reasons classified by
Decreasing Repeat rates
Cause Repeat rates
Equipment Artifacts 40.00%
Blank Image 40.00%
X-Ray Equipment Failure 20.00%
Positioning 0%
Patient Motion 0%
Poor Compression 0%
Improper Detector Exposure 0%
Clinical Artifacts 0%
Incorrect View Marker 0%
QC, Acceptance Tests, Calibration 0%
Interventional Image (e.g., wire loc.) 0%
Other 0%
Decreasing Reject rates
Cause
Blank Image 40.00%
Positioning 40.00%
Incorrect View Marker 20.00%
Equipment Artifacts 0%
X-Ray Equipment Failure 0%
Patient Motion 0%
Poor Compression 0%
Improper Detector Exposure 0%
Clinical Artifacts 0%
QC, Acceptance Tests, Calibration 0%
Interventional Image (e.g., wire loc.) 0%
Other 0%
A GE Healthcare tool
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- To print the results, select Print in the File menu of Internet Explorer.
- To return to the Selection page, click the blue arrow at the bottom of the Results page.
- To close the tool, close Internet Explorer (select Close in the File menu).

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10 Compression Force Test

- Frequency:
  On first installation and then every six months. See Chapter 3 *Guidance* section *7 Compression Force Test on page 105* for additional information.
- Objective:
  To assure that the mammographic system can provide adequate compression in power driven and manual modes and that the equipment does not allow too much compression to be applied.
- Procedure:
  1. This test is not specific to digital mammographic systems. Follow accepted mammographic QC procedures to perform this test. See Chapter 3 *Guidance* section *7 Compression Force Test on page 105*.
  2. Record the compression force on *Chart 5. Record of Checks on page 47*.

  Note:
  1 decaNewton (daN) = 2.2 lbs.
- Action Limit:
  The maximum compression force for the initial power drive must be between 11 and 20 daN (25 to 45 lb.).
- Use of Test Results:
  If the specified results are not obtained, the source of the problem must be identified, and corrective action taken, before any further mammographic images are acquired using the Senographe DS FFDM system that failed. See Chapter 3 *Guidance* section *7 Compression Force Test on page 105*.

The applicable MQSA Quality Mammography Standard is:

900.12(e)(4)(iii)
Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

(iii) Compression device performance.

(A) A compression force of at least 111 newtons (25 pounds) shall be provided.

(B) Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 200 newtons (45 pounds).

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11 Printer

To ensure optimal quality of the film printer output, follow the QC program developed by the manufacturer of the device.

If the printer is used with a film processor incorporating wet chemistry processing, follow the QC program developed by the manufacturer of the printer. If such documentation is not available, refer to Chapter 3 *Guidance* section *1 Wet Chemistry Film Processing on page 101*.

- Action Limit:
  The printer must pass all of the printer manufacturer's QC tests.
- Use of Test Results:
  If the printer fails a test, the source of the problem must be identified, and corrective action taken, before the printer is used for any further reviews.

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12 Test Results Record Forms

Chart 1. Daily and Weekly Tests

Facility: _____ Room: _____

Year								Month								
Date	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Initials																
Monitor cleaning (daily)																
Flat Field test (weekly)																
Image Quality test (weekly)																
Viewing Conditions (weekly)																

Year								Month								
Date	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Initials																
Monitor cleaning (daily)																
Flat Field test (weekly)																
Image Quality test (weekly)																
Viewing Conditions (weekly)																

Remarks: _____

_____

_____

_____

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Chart 2. Image Quality and MTF Measurement Test Record (1/3)

Use this form to record the results of Flat Field, Phantom Image Quality and CNR and MTF Measurement tests:

Year														
Month														
Date														
Initials														
Flat Field			Test object used:								Mark Pass/Fail			
Brightness non-uniformity														
High frequency modulation														
Bad pixel verification														
Bad ROI														
SNR non-uniformity														
Phantom Image Quality			Phantom Used:											
AWS:														
Zoom														
Window Width (WW)														
Window Level (WL)														
No. of fibers														
No. of specks groups														
No. of masses														
Printer:														
No. of fibers														
No. of speck groups														
No. of masses														

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Chart 2. Image Quality and MTF Measurement Test Record (2/3)

Determination of Operating Level CNR

	Date	CNR	Date	CNR	Date	CNR
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
CNR_{ol}						

CNR_{ol} (Operating Level CNR) = Average of 5 CNR values, one acquired on each of five consecutive days.

Notes:

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Chart 2. Image Quality and MTF Measurement Test Record (3/3)

Year									
Month									
Date									
Initials									
MTF + CNR Measurements		IQST Device Reference No:							
MTF parallel at 2 lp/mm									
MTF parallel at 4 lp/mm									
MTF perpendicular at 2 lp/mm									
MTF perpendicular at 4 lp/mm									
Contrast-to-Noise Ratio (CNR)									
Change in CNR									

Notes:

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Chart 3. AOP Mode and SNR Check Records

Frequency: *Monthly*

Room: . . . . . Unit: . . . . . .

Year	Month												
	Date												
	Initials												
AOP Mode Check; mAs or F/n. *See* Chapter 3 *Guidance section* 5 *AOP Mode and SNR Check on page 103* regarding a method to record these results.													
25 mm acrylic													
50 mm acrylic													
60 mm acrylic													
AOP Mode Check; SNR values:													
25 mm acrylic													
50 mm acrylic													
60 mm acrylic													

Notes:

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Chart 4. Visual Checklist Record

Frequency: *Monthly*

Room: . . . . . Unit: . . . . . .

Year:												
Month												
Day												
Initials												
Gantry:												
Angulation Indicator												
Locks (all)												
Field Light												
Smoothness of motion												
Inspect all paddles for cracks												
Control Panel:												
Switches/indicators												
Display												
Technique charts												
Other:												
Cleaning fluid												

Pass: P
Fail: F
Does not Apply: N/A

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Chart 5. Record of Checks

Year	Month												
	Date												
	Initials												
Visual Inspection													
Repeat Analysis													
Compression:	Auto												
	Manual												
Radiologist Review													
Physicist Review													

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Chart 6. Repeat Exposure Record Sheet - Manual Method

Use this chart to record all repeated exposures that caused the patient to receive additional dose beyond that of the normal exam.

Period covered:

Dates . . . . . From . . . . . To . . . . . .

Study #	Causes	No. of Times	Date	Technologist

Causes:

1 Positioning
2 Patient Motion
3 Exposure too low (noisy image)
4 Exposure too high (image saturation)
5 Incorrect Patient ID
6 X-ray Equipment Failure
7 Blank Image
8 Other

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Chart 7. Repeat Exposure Analysis - Manual Method

Use this chart to analyze all repeated exposures that caused the patient to receive additional dose beyond that of the normal exam.

Period covered:

Dates . . . . . From . . . . . To . . . . . .

Cause		No. of Repeat Exposures	Percentage of Repeats by category
1	Positioning		
2	Patient Motion		
3	Exposure too low (noisy image)		
4	Exposure too high (image saturation)		
5	Incorrect Patient ID		
6	X-ray Equipment Failure		
7	Blank Image		
8	Other		

Total of Repeat Exposures (R)	
Total of All Exposures (T)	
Repeat Exposure Percentage (R/T x 100)	

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Chart 8. Repeat and Reject Exposure Analysis - Automated Method

Use this chart to record the analysis of repeated and rejected exposures.

Period covered:

Dates . . . . . From . . . . . To . . . . . .

Cause	Number of Repeats	Percentage of Repeats	Number of Rejects	Percentage of Rejects
Positioning				
Patient Motion				
Poor Compression				
Improper Detector Exposure				
X-Ray Equipment Failure				
Equipment Artifacts				
Blank Image				
Clinical Artifacts				
Incorrect View Marker				
QC, Acceptance Tests, Calibration				
Interventional Image (e.g., wire loc.)				
Other				

Total Repeats + Rejects	
Total Repeats	
Total Rejects	
Non-Clinical Repeats+Rejects	
Total number of exposures	
Total Repeat+Reject rate	
Total Repeat rate	
Clinical Repeat rate	

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Chapter 2 QC Tests for the Medical Physicist

1 Introduction

The QC tests listed in this section must be performed by the Medical Physicist to ensure that the Senographe DS provides a high level of mammographic image quality. These tests also form the basis of the mammography equipment evaluation (MEE) that must be performed following the installation of a new mammography system or the repair or replacement of a major component of the system. Additional information regarding MEEs can be found in Chapter 3 *Guidance* section *15 Summary of Mammography Equipment Evaluation on page 110* and a form to summarize the results of the evaluation is included following that section.

- The following tests are described in Chapter 1 *QC Tests for the Radiologic Technologist*:

Radiologic Technologist's QC section		Minimum Frequency	Section
1.	Flat Field and Phantom IQ Tests	Annually	*Chapter 1* section *4 Flat Field and Phantom IQ Tests on page 16*
2.	CNR and MTF Measurement *	Annually	*Chapter 1* section *5 CNR and MTF Measurement on page 21*
3.	AOP Mode and SNR Check	Annually	*Chapter 1* section *7 AOP Mode and SNR Check on page 24*

* The physicist may substitute *Job Card VF-P02A - Sub-System MTF Measurement on page 71* for the two tests *CNR and MTF Measurement on page 21* and *Job Card VF-P02 - Evaluation of Focal Spot Performance on page 65*.

Note:

GE recommends that Standard (STD) and Dose (DOSE) mode be used for routine mammography.

Contrast (CNT) mode of the Senographe DS delivers more dose than Standard (STD) and Dose (DOSE) modes.

GE recommends that Contrast (CNT) mode be used only after consultation with an interpreting physician or radiologist.

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- Additional tests that must be performed by the Physicist are listed below:

Specific to Digital Mammography		Minimum Frequency	Section
4.	Collimation Assessment	Annually	*Job Card VF-P01 - Collimation Assessment*
5.	Evaluation of Focal Spot Performance *	Annually	*Job Card VF-P02 - Evaluation of Focal Spot Performance*
6.	Sub-system MTF Measurement *	Annually	*Job Card VF-P02A - Sub-System MTF Measurement*
7.	Breast Entrance Exposure, Average Glandular Dose, and Reproducibility	Annually	*Job Card VF-P03 - Breast Entrance Exposure, Average Glandular Dose and Reproducibility*
8.	Artifact Evaluation; Flat Field Uniformity	Annually	*Job Card VF-P04 - Artifact Evaluation and Flat Field Uniformity*

* The physicist may substitute *Job Card VF-P02A - Sub-System MTF Measurement on page 71* for the two tests *CNR and MTF Measurement on page 21* and *Job Card VF-P02 - Evaluation of Focal Spot Performance on page 65*.

Tests 4 through 7 are described in Job Cards VF-P01 through VF-P04.

Charts for recording the results of the tests are provided as Charts 0-4.

Not Specific to Digital Mammography		Minimum Frequency	Section
9.	kVp Accuracy and Reproducibility	Annually	*Chapter 3* section *9-1 kVp Accuracy and Reproducibility on page 106*
10.	Beam Quality Assessment (Half-value Layer Measurement)	Annually	*Chapter 3* section *9-2 Beam Quality Assessment on page 106*
11.	Radiation Output	Annually	*Chapter 3* section *9-3 Mammography Unit Assembly Evaluation and Radiation Output on page 106*
12.	Mammographic Unit Assembly Evaluation	Annually	*Chapter 3* section *9-3 Mammography Unit Assembly Evaluation and Radiation Output on page 106*

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The MQSA Quality Mammography Standards applicable to the last four tests are:

900.12(e)(5)(ii)
Kilovoltage peak (kVp) accuracy and reproducibility.
(A) The kVp shall be accurate within ± 5 percent of the indicated or selected kVp at:
(1) The lowest clinical kVp that can be measured by a kVp test device;
(2) The most commonly used clinical kVp;
(3) The highest available clinical kVp, and
(B) At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.
900.12(e)(5)(iv)
Beam quality and half-value layer (HVL).
The HVL shall meet the specifications of Sec. 1020.30(m)(1) of this chapter for the minimum HVL. These values, extrapolated to the mammographic range, are shown in the table below. Values not shown in the table below may be determined by linear interpolation or extrapolation.

X-ray Tube Voltage (kilovolt peak) and Minimum HVL		
Designed Operating Range (kV)	*Measured Operating Voltage (kV)*	*Minimum HVL (millimeters of aluminum)*
Below 50	*20*	*0.20*
	25	*0.25*
	30	*0.30*

900.12(b)(3)
Motion of tube-image receptor assembly.
(i) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.
(ii) The mechanism ensuring compliance with paragraph (b)(3)(i) of this section shall not fail in the event of power interruption.
900.12(e)(5)(x)
Radiation output.
(A) The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 milliRoentgen (mR) per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.
(B) The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

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900.12(e)(5)(xi)
Decompression.
If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:
(A) An override capability to allow maintenance of compression;
(B) A continuous display of the override status; and
(C) A manual emergency compression release that can be activated in the event of power or automatic release failure.

ORDER OF PERFORMING THE TESTS

To minimize the effect of the test procedures on the assessment of field uniformity and inspection for artifacts, perform the tests in the following order:

1. Flat Field test, Chapter 1, section 4-1, but do not do Phantom IQ tests at this time.

2. Artifact Evaluation; Flat Field Uniformity, Chapter 2, Job Card VF-P04 - Artifact Evaluation and Flat Field Uniformity.

3. Remaining tests, including Phantom IQ tests, Chapter 1, section 4-2.

WHEN PERFORMING THE PROCEDURES:

- *All processed images in Medical Application are in logarithmic format. To make measurements on an image acquired in Medical Application, the Raw image (which is in linear format) must be used. In addition to that, a physicist's measurements (e.g. MTF and noise) performed using methods other than those described in this manual can be affected when Fineview processing is applied.*
- *When test procedures are run which do not require the capture of X-rays by the detector and require the presence of an object in the X-ray beam (e.g., the measurement of dose using a dosimeter), the detector must be protected by a 3 mm thick (minimum) steel plate or equivalent attenuator. This will prevent any possibility of ghost images.*

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Chart 0. Site and System Summary

Facility Name: _____

Address: _____

_____

_____

Date of Installation _____

Date of Survey _____

Room ID _____

Serial Numbers _____

Mammographic Unit _____

Medical Physicist _____

Signature _____

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Job Card VF-P01 - Collimation Assessment

- Objective:
  To ensure that there is no excessive extension of the X-ray field beyond the edges of the image receptor, that the X-ray field aligns with the light field, and that the chest wall edge of the compression paddle aligns with the chest wall edge of the image receptor (digital detector).
- Required Test Equipment:
  - Five coins, four of one size (e.g., pennies or 1-eurocent coins), one of a larger size (e.g., a nickel or a 5-eurocent coin).
  - An auxiliary image receptor sufficiently large to extend beyond the edges of the 19 cm x 23 cm field of view of the primary image receptor, i.e., the digital detector. This may be a 24 cm x 30 cm mammographic cassette with film. This auxiliary image receptor may also be a general radiographic screen-film cassette or a computed radiography (CR) cassette. It is also permissible to use a set of small image receptors positioned at each location where an image of the edge of the field is to be acquired.
- Procedure:
  Exposures
  1. Install the Bucky on the image receptor.
  2. Set the collimator to the maximum field size.
  3. Position the auxiliary image receptor to intercept the four edges of the x-ray field.
  4. Remove the compression paddle to assure a sharp demarcation at the edge of the light field.
  5. Turn on the collimator light and place one of each of the four identical smaller coins on the auxiliary image receptor and inside each edge of the light field, with the edge of the coin just touching the edge of the light field.
  6. Tape the larger coin to the underside of the compression paddle, tangent to the inner, vertical surface of the compression paddle at the chest wall edge to mark the inner chest wall edge of the compression paddle. Position the coin near the center of the chest wall edge, but at a location where its image will not interfere with the image of the coin marking the chest wall edge of the light field.
  7. Replace the compression paddle and position it approximately 4.2 cm from the breast support.
  8. Make an exposure using parameters that will provide usable signals on both the primary and auxiliary image receptors.

  Note:
  If it is not possible to obtain usable signals on both image receptors using a single exposure, it will be necessary to acquire the data from two exposures, one with the auxiliary image receptor in the field and a second with it removed. Position each coin at the same relative position along the edge of the light field for each exposure.
  9. Perform Steps 1 through 8 for the large focal spot of both the Mo and the Rh anode tracks.

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- Measurements:
  In this section, the image acquired from the auxiliary image receptor will be referred to as the *film*. From the film and AWS (Acquisition WorkStation), measure the appropriate dimensions for the following tests. Use the *Segment* tool on the AWS for measurements on the primary image receptor. Measurements both from the film and the AWS must be scaled to the primary image receptor plane.

1. From the film image, determine the deviations Y_f, between the x-ray field and the light field at each edge of the field. If the coin is only partially visible, as shown in *Illustration 1*, Y_f can be determined as

   $$Y_f = W_f - P_f \qquad \text{Eq. 1}$$

   where

   W_f = the diameter of the coin as measured from the film and

   P_f = the partial diameter of the coin measured perpendicular to the edge of the x-ray field.

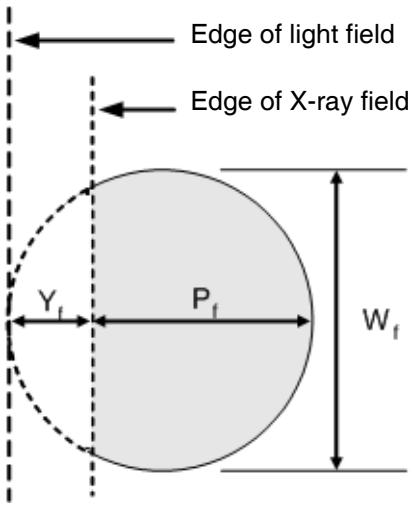

Illustration 1 Image on film; coin at edge of light field

2. From the AWS, use the **Segment** tool to determine the deviations, X, between the edge of the x-ray field and the edge of the image receptor at each edge of the field.

   Note:
   The reference plane of the **Segment** tool is located 2 cm above the breast support surface. Hence, to scale **Segment** tool measurements to the image receptor plane, apply the following scaling:

   $$X = X' \bullet M \qquad \text{Eq. 2}$$

   where
   X = the measurement referenced to the image receptor plane,
   X' = the measurement made using the **Segment** tool,
   M = 1.063
   When the edge of the x-ray field is visible in the digital image, the distance between the edge of the x-ray field and the edge of the image receptor is measured directly using the **Segment** tool and application of the magnification factor, M, as indicated in Eq. 2.

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In other cases, the deviation between the x-ray field and the image receptor, can be determined as follows:

a. If the light field is outside of the x-ray field and the x-ray field is outside the image receptor, as shown in *Illustration 2*, then

$$X = X' \bullet M = (W_d - P_d - Y_d) \bullet M \qquad \text{Eq. 3}$$

where

W_d = the diameter of the coin measured in the digital image,

P_d = the partial diameter of the coin measured perpendicular to the edge of the image receptor, and

Y_d = the deviation between the light field and the x-ray field scaled to the **Segment** tool reference plane.

Y_d is calculated as

$$Y_d = Y_f \times (W_d / Wf) \qquad \text{Eq. 4}$$

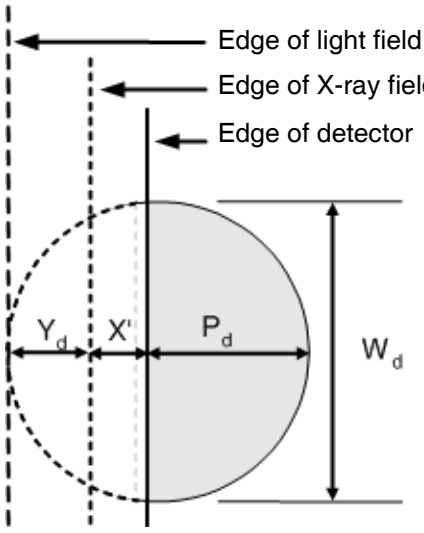

Illustration 2 Image on AWS; coin at edge of light field, light field outside X-ray field

b. If the x-ray field is outside of the light field and both are outside the image receptor, as shown in *Illustration 3*, then

$$X = (W_d - P_d + Y_d) \bullet M \qquad \text{Eq. 5}$$

c. If the x-ray field is outside of the light field, and the edge of the image receptor is between the two, as shown in *Illustration 4*, then

$$X = (Y_d - F) \bullet M \qquad \text{Eq. 6}$$

where

F = the measured perpendicular distance from the image receptor edge to the coin image edge in the digital image.

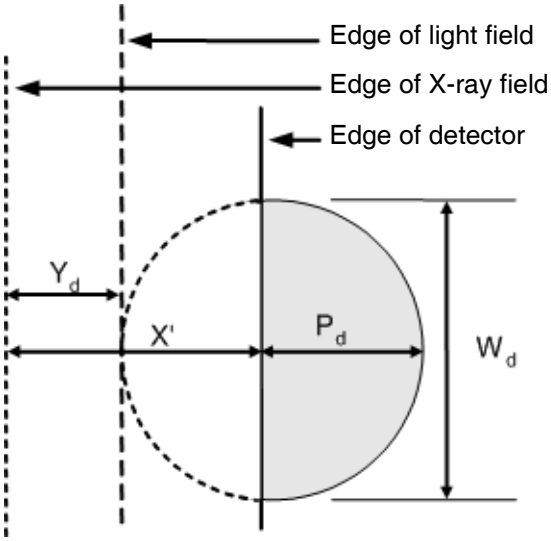

Illustration 3 Image on AWS; coin at edge of light field, X-ray field outside light field

3. Convert all deviations Y_f measured in the film plane to deviations in the image receptor plane using Eq. 4 and the scaling factor M.
4. Enter measured deviations between X-ray field and light field on the data form as follows:
   - The magnitudes of deviations at the left edge and right edge (ignoring + or - signs) are entered on the data form and added together.
   - Similarly, the deviations at the anterior and posterior (chest wall) edges are entered (without regard to sign) and the magnitudes added together.

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5. Measure the deviation between the alignment of the edge of the compression paddle (delineated by the outer edge of the large coin) and the edge of the image receptor. Scale the distances to the plane of the image receptor as described by Eq. 2.
6. Perform the test for both the Mo and Rh target materials.
7. Check that the chest wall edge of the x-ray field extends to the chest wall edge of the image receptor.
8. Check that the vertical edge of the compression paddle is not visible in the image.

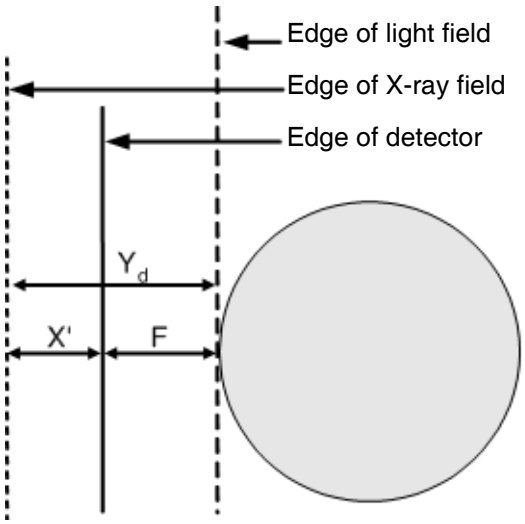

Illustration 4 Image on AWS; coin at edge of light field, X-ray field outside light field

- Action Limit:

  Congruence of the light field with the X-ray field must be such that the total misalignment (sum of misalignments on opposite sides) is within 2% of the SID.

  The X-ray field must extend at least to the edge of the active image receptor at the chest wall. The X-ray field must not extend beyond any edge of the image receptor by more than 2% of the SID, 1.3 cm extension for a 66 cm SID.

  The chest wall edge of the compression paddle must be aligned just beyond the chest wall edge of the image receptor such that the chest wall edge of the compression paddle does not appear in the mammogram. In addition, the chest wall edge of the compression paddle must not extend beyond the chest wall edge of the image receptor by more than 1% of the SID.
- Use of Test Results:

  If the Action Limits are not met, the source of the problem shall be identified and corrective actions shall be taken within 30 days of the test date. *See* Chapter 3 *Guidance* section *10 Collimation Assessment on page 106*.

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The applicable MQSA Quality Mammography Standard is:

900.12(e)(5)(vii)

X-ray field/light field/image receptor/compression paddle alignment.

(A) All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the X-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.

(B) If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.

(C) The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

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Chart 1 - Collimation Assessment

Date: . . . . . .
Source to Image Receptor Distance (SID): . . . . . .

Deviation between X-ray field and light field:			
Field of View			
X-ray Tube Target			
Left Edge Deviation			
Right Edge Deviation			
Sum of magnitudes of left and right edge deviations			
Sum as % of SID			
Anterior Edge Deviation			
Chest Wall Edge Deviation			
Sum of magnitudes of anterior and chest edge deviations			
Sum as % of SID			
Use of Test Results: If the sum of left plus right deviations or anterior plus chest wall edge deviations exceeds 2% of the SID, the source of the problem must be identified and corrective action taken within 30 days of the test date.			

Deviation between X-ray field and image receptor			
Field of View			
X-ray Tube Target			
Left Edge Deviation (absolute)			
Left Edge Deviation (% of SID)			
Right Edge Deviation (absolute)			
Right Edge Deviation (% of SID)			
Anterior Edge Deviation (absolute)			
Anterior Edge Deviation (% of SID)			
Chest Wall Edge Deviation (absolute)			
Chest Wall Edge Deviation (% of SID)			
Chest wall edge of the field extends to the chest wall edge of the image receptor (yes/no)			
Use of Test Results: If the entire chest wall edge of the x-ray field does not extend to the chest wall edge of the image receptor, or if the X-ray field extends beyond the image receptor by more than 2% of SID, the source of the problem must be identified and corrective action taken within 30 days of the test date.			

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Alignment of chest wall edges of compression paddle and image receptor			
X-ray Tube Target			
Paddle Size			
Difference between compression paddle edge and image receptor edge at chest wall (absolute)			
Difference (% of SID), edge visible (Yes/No)			
Paddle Size			
Difference between compression paddle edge and image receptor edge at chest wall (absolute)			
Difference (% of SID), edge visible (Yes/No)			
Paddle Size			
Difference between compression paddle edge and image receptor edge at chest wall (absolute)			
Difference (% of SID), edge visible (Yes/No)			
Paddle Size			
Difference between compression paddle edge and image receptor edge at chest wall (absolute)			
Difference (% of SID), edge visible (Yes/No)			
Use of Test results: If the chest wall edge of the compression paddle is within the image receptor or projects beyond the chest wall edge of the image receptor by more than 1% of SID, the source of the problem must be identified and corrective action taken within 30 days of the test date.			

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Job Card VF-P02 - Evaluation of Focal Spot Performance

- Objective:
  To evaluate focal spot performance by using a high-contrast resolution pattern.

  Note:
  The physicist may substitute *Job Card VF-P02A - Sub-System MTF Measurement on page 71* for the two tests *CNR and MTF Measurement on page 21* and *Job Card VF-P02 - Evaluation of Focal Spot Performance on page 65*.
- Required Test Equipment:
  - High-contrast resolution bar pattern for use in mammographic system evaluation providing spatial frequencies up to 16 lp/mm and preferably 20 lp/mm. The thickness of the pattern shall not exceed 0.025 mm.
  - A film-based image receptor, for example, either a direct exposure, ready-pack film (such as Kodak XTL-2) or a loaded mammographic screen-film cassette for which the screen-film combination does not limit the measured resolution (this can be tested by imaging the test pattern in contact with the cassette).
  - Acrylic block, 4.5 cm thick and approximately 10 cm x 10 cm in cross-section.
  - Lead marker to designate the anode-cathode axis direction.
  - An optical magnifier providing 10x to 30x magnification.
- Procedure:
  1. Remove the compression paddle.
  2. Place the film-based image receptor on top of the breast support surface.
  3. Place the 4.5 cm block on the film-based receptor and place the bar pattern on top of the block. Place the lead marker on the receptor to indicate the direction of the anode-cathode axis.
  4. To measure the limiting resolution of the focal spot width,
     - Orient the pattern's bars parallel to the anode-cathode axis.
     - Position the edge of the pattern within 1 cm of the chest wall edge of the digital image receptor, centered laterally.

  Note:
  It is important that the test pattern be positioned in a reproducible manner. See Chapter 3 *Guidance* section *11 Evaluation of FocalJ Spot Performance on page 106*.
  5. Select the manual exposure control mode, molybdenum target material, large focal spot, and the kVp, mAs, and filter material used for imaging an average breast during normal mammography.
  6. Make an exposure.
  7. Remove the film-based image receptor, replace it with an unexposed one, and reposition the acrylic block and bar pattern.
  8. To measure the limiting resolution of the focal spot length,
     - Orient the pattern's bars perpendicular to the anode-cathode axis with the lowest frequency pattern nearest the chest wall edge of the digital image receptor.
     - Position the edge of the pattern within 1 cm of the chest wall edge of the digital image receptor, centered laterally.
  9. Make a second exposure.
  10. Repeat steps 1 through 9 for the rhodium target material using the same geometry.

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11. If the small focal spot is used clinically, evaluate the molybdenum and rhodium targets of the small focal spot in magnification mode with the resolution pattern positioned 4.5 cm above the magnification breast support and a magnification factor of 1.5 X.
    a. Remove the Bucky and install the 1.5X magnification stand.
    b. Place the 4.5 cm block on the breast support surface of the magnification stand and place the bar pattern on top of the block.
    c. Place the film-based image receptor on the detector cover.
    d. Repeat steps 4 through 9 for each target material. Note that it will not be necessary to reposition the acrylic block as stated in step 7.
12. Under masked viewbox conditions, view the high-contrast resolution pattern images with 10x to 30x magnification.
13. Note the highest frequency pattern whose lines are distinctly visible throughout at least half of the bar length and record the highest frequency visible for each test image.

- Action Limit:

  In the contact mode or the 1.5X magnification mode, measurements made with the bars parallel to the anode-cathode axis must be at least 13 lp/mm; measurements with the bars perpendicular to the anode-cathode axis must be at least 11 lp/mm.
- Use of Test Results:

  If the above specifications are not met, the source of the problem must be identified and corrective action taken within 30 days of the test date. Refer to Chapter 3 *Guidance* section *11 Evaluation of FocalJ Spot Performance on page 106* for additional information.

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The applicable MQSA Quality Mammography Standard is:

900.12(e)(5)(iii)

Focal spot condition.

Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.

(A) System Resolution.

(1) Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 Cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

(2) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

(3) When more than one target material is provided, the measurement in paragraph (e)(5)(iii)(A) of this section shall be made using the appropriate focal spot for each target material.

(4) When more than one SID is provided, the test shall be performed at SID most commonly used clinically.

(5) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

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Chart 2 - Evaluation of Focal Spot Performance

High contrast resolution pattern measurement of focal spot limiting resolution.

Resolution Test Tool: . . . . . .
Patient ID #: . . . . . .

Nominal Focal Spot Size, f_{nom}				
Anode track				
Nominal kVp setting				
mAs				
Magnification Factor	Contact			
Limiting Resolution				
Bars parallel to A-C axis				
Bars perpendicular to A-C axis				
Action Limit: In the contact configuration or the 1.5 X magnification configuration, measurements made with the bars parallel to the anode-cathode axis must be at least 13 lp/mm; measurements with the bars perpendicular to the anode-cathode axis must be at least 11 lp/mm. Use of Test Results: If the above specifications are not met, the source of the problem must be identified and corrective action taken within 30 days of the test date.				

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Job Card VF-P02A - Sub-System MTF Measurement

- Objective:

  The test is designed to ensure that contrast is adequate over the 0 to 5 lp/mm spatial frequency range at the detector plane, by obtaining an estimate of the Sub-System MTF (Modulation Transfer Function) at object frequencies of 2.09 and 3.93 lp/mm for the large focal spot and at object frequencies of 5 and 8 lp/mm for the small focal spot at 1.8X magnification. The result obtained is a measure of the MTF of the sub-system consisting of the x-ray tube focal spot and the detector.

CAUTION

To perform this measurement it is necessary that the image processing algorithm FineView be disabled. If the FineView algorithm is normally enabled during clinical use, you must re-enable FineView at the completion of this measurement.

Note:

This procedure provides a measurement of the sub-system resolution of the FFDM image acquisition system without the need for film. When performing a QC survey or mammography equipment evaluation of a Senographe DS, the physicist may use this procedure instead of the following two tests:

CNR and MTF Measurement, Chap. 1, Sec. 5
Evaluation of Focal Spot Performance, Chap. 2, Job Card VF-P02

- Equipment required:
  - Resolution bar pattern including spatial frequency groups of 2.09 and 3.93 lp/mm and having a thickness equivalent to at least 0.1 mm of lead. Suitable bar patterns are identified in Chapter 3 *Guidance* section *12-1 Suitable Bar Patterns on page 107*.
  - Resolution bar pattern including spatial frequency groups of 5 and 8 lp/mm and having a thickness equivalent to at least 25 µm of lead. For this bar pattern:
    - The distance from the low-frequency end of the bar pattern to the center of the 5 lp/mm pattern group must be no greater than 6 mm.
    - The distance from the low-frequency end of the bar pattern to the center of the 8 lp/mm pattern group must be no greater than 12 mm.

    Suitable bar patterns are identified in Chapter 3 *Guidance* section *12-1 Suitable Bar Patterns on page 107*.
  - Acrylic block or stack of acrylic plates, 4.5 cm thick and at least 12 cm x 12 cm in cross-section. The trapezoidal acrylic plates used for the *AOP Mode and SNR Check* may also be used for this measurement by following the specific instructions included in this procedure. Suitable material is provided with Senographe DS systems for facilities subject to the rules of the United States Mammography Quality Standards Act and optionally available to other facilities.

Note:

In this procedure, whether the 4.5 cm of acrylic used to support the bar pattern consists of a single block or a stack of plates, it is referred to as the *acrylic block*.

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Note:
Certain resolution test devices contain two bar patterns positioned at right angles to each other. Concerns regarding these patterns include the angle between the two patterns and the ability to position the patterns according to the requirements of this procedure. For additional information see Chapter 3 *Guidance* section *12-3 Use of Dual-Orthogonal Test Patterns for the MTF Measurement on page 107*.

Note:
Inaccurate bar pattern frequencies can lead to systematic errors in the MTF. See Chapter 3 *Guidance* section *12-4 Bar Pattern Frequency Inaccuracy on page 108* regarding bar pattern frequency inaccuracy and section *12-5 Sensitivity of MTF Measurement to Bar Pattern Frequency Error on page 108* regarding sensitivity of the MTF to spatial frequency error.

Note:
To avoid false results, the bar patterns and the acrylic block must be clean and free from scratches.

Note:
To allow for temperature stabilization of the detector, the system must be powered on for at least 10 minutes before performing any measurements related to detector image quality. If any test is not passed after allowing a 10-minute warm-up period, see Chapter 3 *Guidance* section *12-8 Actions to be taken if specifications are not met on page 109*.

- Procedures:
  The procedures necessary for Sub-System MTF measurement are described under the following headings:
  - *Procedure 1 - Disable FineView on page 73*.
  - *Procedure 2 - Preparation for Large Focal Spot exposures on page 73*.
  - *Procedure 3 - Setup and exposures for MTF measurements of large focal spot width on page 74*.
  - *Procedure 4 - Setup and exposures for MTF measurements of large focal spot length on page 76*.
  - *Procedure 5 - Preparation for Small Focal Spot exposures on page 78*.
  - *Procedure 6 - Setup and exposures for MTF measurements of small focal spot width on page 78*.
  - *Procedure 7 - Setup and exposures for MTF measurements of small focal spot length on page 80*.
  - *Procedure 8 - Measurements on images acquired using the large focal spot on page 82*.
  - *Procedure 9 - Measurements on images acquired using the small focal spot on page 84*.
  - *Procedure 10 - Analysis of MTF measurements on page 87*.
  - *Procedure 11 - Restore FineView Setting on page 88*.

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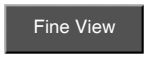
- Procedure 1 - Disable FineView

  1. From the Browser click the **Tools menu** button (near the top right of the Browser screen) to display the utilities menu.
  2. Select **Medical Application preferences** from the drop-down menu.
  3. In the *Medical Application preferences* window, click on the button labeled *Fine View* 

  or *Image Process*

  .
  4. Record the current FineView status in *Chart 2A - Sub-System MTF Measurement on page 89*.
  5. If FineView is enabled:

     - Disable FineView.

     - Click **Save**.

     - Click **Close**.

  6. If FineView is already disabled:

     - Click **Close**.

- Procedure 2 - Preparation for Large Focal Spot exposures
  1. Run the normal Medical Application.
  2. Open a new patient (named, for example, *Sub-System MTF)* in the Medical Application.
  3. Install the Bucky on the image receptor if it is not already installed.
  4. Remove the compression paddle.
  5. Set the collimator for the maximum field size.

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- Procedure 3 - Setup and exposures for MTF measurements of large focal spot width

1. Position the acrylic block and the bar pattern that includes the 2.09 and 3.93 lp/mm groups on the breast support surface of the Bucky as follows:

   If you are using a square acrylic block:

   Refer to *Illustration 1*.

   Align one side of the block with the chest-wall edge of the Bucky and center the block left-to-right.

   Position the bar pattern on the block so that the pattern is centered left-to-right, and so that the bars are parallel to the anode-cathode axis (perpendicular to the chest wall edge of the Bucky).

   The edge of the pattern must be within 1 cm of the chest wall edge of the image receptor (see *Illustration 3*).

Note:

The requirement for the position of the edge of the pattern (see *Illustration 3*) is referenced to the image receptor, not to the image. For the large focal spot, the distance from the chest wall edge of the image receptor to the edge of the pattern must not exceed 10.5 mm when measured from the image using the *Segment* tool.

If you are using a trapezoidal acrylic block:

Refer to *Illustration 2*.

Align one of the non-parallel sides of the block with the chest wall edge of the Bucky.

Position the bar pattern on the block so that the bars are parallel to the anode-cathode axis (perpendicular to the chest wall edge of the Bucky), and so that one of the corners at the low-frequency end of the bar pattern is tangent to the shorter base of the trapezoid at the mid-point of the base.

Move the block and pattern together to center the pattern left-to-right.

2. Select the manual exposure control mode and set the following parameters:

   Mo target; Mo filter; 30 kVp; 140 mAs.

3. Select Left breast laterality and make an exposure.
4. Select the manual exposure control mode and set the following parameters:

   Rh target; Rh filter; 30 kVp; 140 mAs.

5. Select Left breast laterality and make an exposure.

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Illustration 1 MTF evaluation of large focal spot width - Positioning of square acrylic block and bar pattern

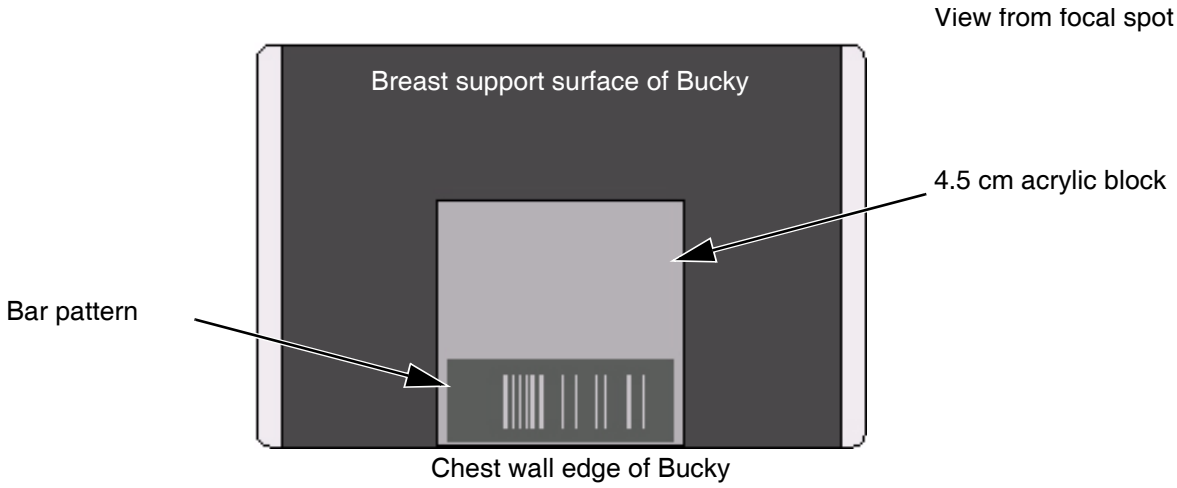


Illustration 2 MTF evaluation of large focal spot width - Positioning of trapezoidal acrylic block and bar pattern

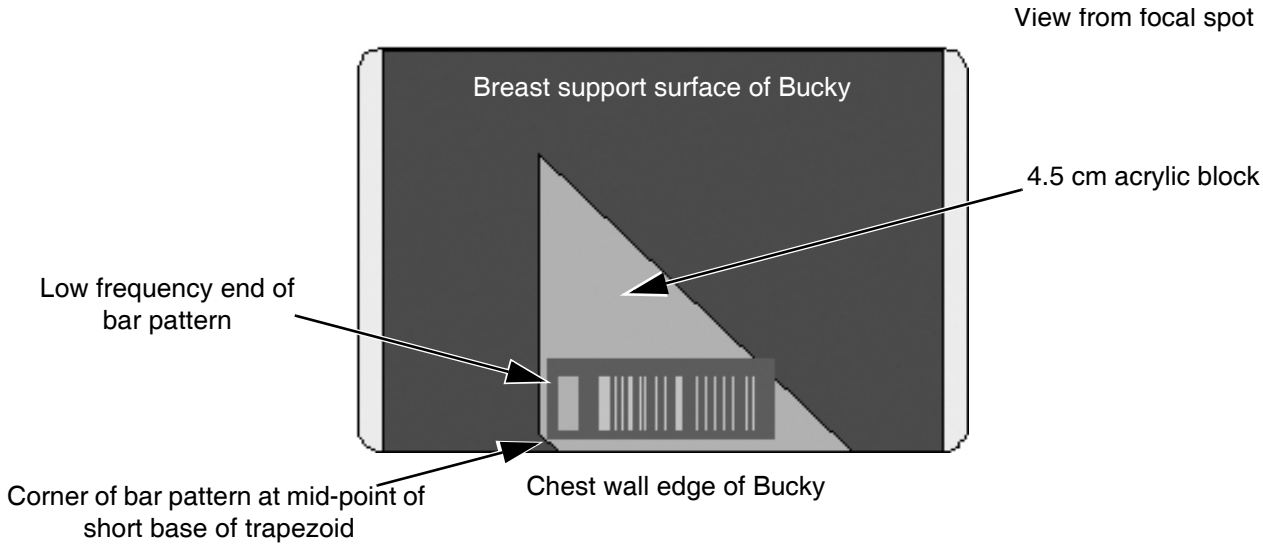
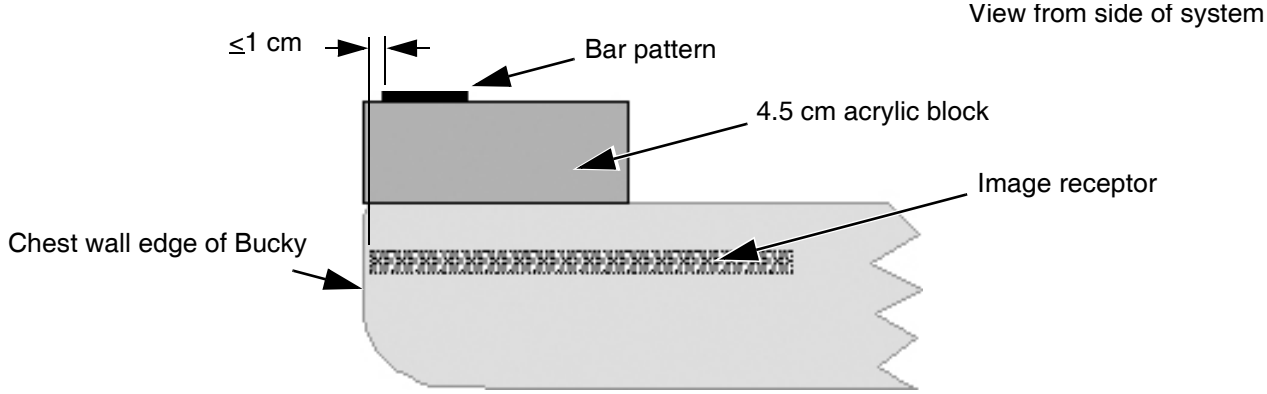

View from focal spot
Breast support surface of Bucky
4.5 cm acrylic block
Low frequency end of bar pattern
Corner of bar pattern at mid-point of short base of trapezoid
Chest wall edge of Bucky

Illustration 3 MTF evaluation of large focal spot Length and width - Positioning of acrylic block and bar pattern



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- Procedure 4 - Setup and exposures for MTF measurements of large focal spot length
  1. Position the acrylic block and the bar pattern that includes the 2.09 and 3.93 lp/mm groups on the breast support surface of the Bucky as follows:

     If you are using a square acrylic block:

     Refer to *Illustration 4*.

     Align one side of the block with the chest-wall edge of the Bucky and center the block left-to-right.

     Position the bar pattern on the block so that the pattern is centered left-to-right, and so that the bars are perpendicular to the anode-cathode axis (parallel to the chest wall edge of the Bucky). The edge of the pattern must be within 1 cm of the chest wall edge of the image receptor.

     If you are using a trapezoidal acrylic block:

     Refer to *Illustration 5*.

     Align one of the non-parallel sides of the block with the chest wall edge of the Bucky.

     Position the bar pattern on the block so that the bars are perpendicular to the anode-cathode axis (parallel to the chest wall edge of the Bucky), and so that one of the corners at the low-frequency end of the bar pattern is tangent to the shorter base of the trapezoid at the mid-point of the base.

     Move the block and pattern together to center the pattern left-to-right.
  2. Select the manual exposure control mode and set the following parameters:

     Mo target; Mo filter; 30 kVp; 140 mAs.
  3. Select Left breast laterality and make an exposure.
  4. Select the manual exposure control mode and set the following parameters:

     Rh target; Rh filter; 30 kVp; 140 mAs.
  5. Select Left breast laterality and make an exposure.

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Illustration 4 MTF evaluation of large focal spot length - Orientation of bar pattern on square acrylic block

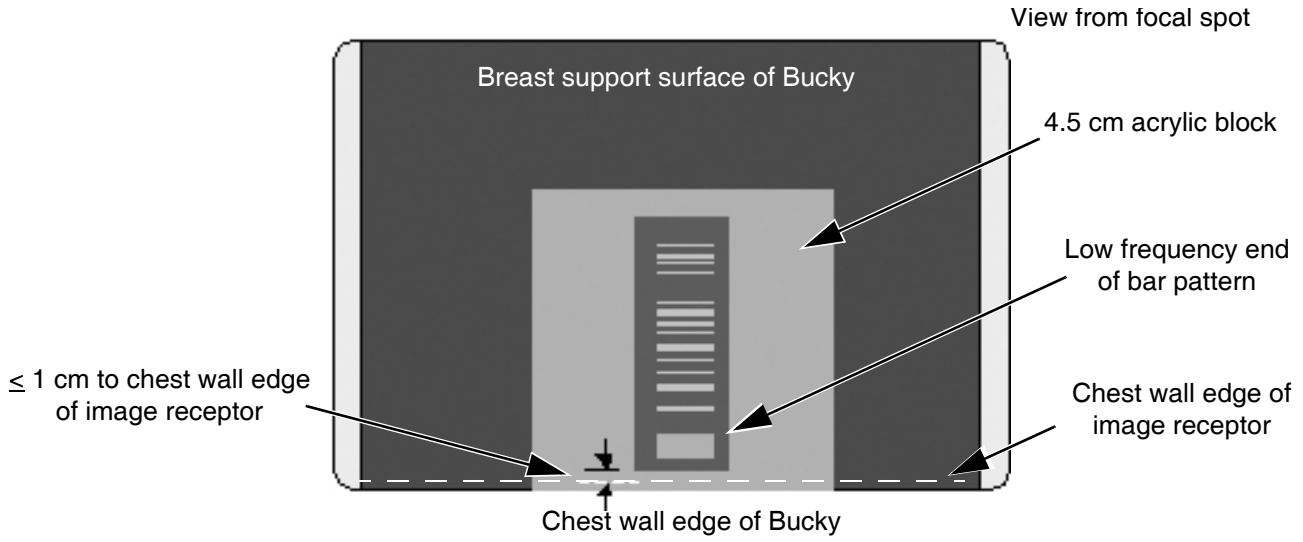
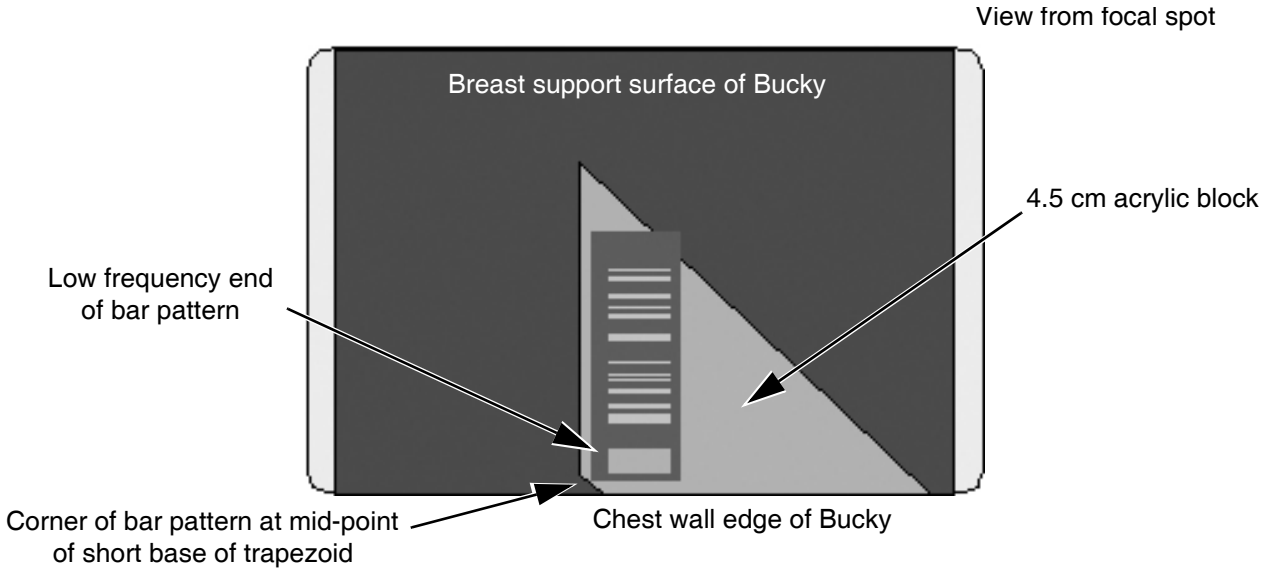

View from focal spot
Breast support surface of Bucky
4.5 cm acrylic block
Low frequency end of bar pattern
≤ 1 cm to chest wall edge of image receptor
Chest wall edge of image receptor
Chest wall edge of Bucky

Illustration 5 MTF evaluation of large focal spot length - Orientation of bar pattern on trapezoidal acrylic block


View from focal spot
Breast support surface of Bucky
4.5 cm acrylic block
Low frequency end of bar pattern
Corner of bar pattern at mid-point of short base of trapezoid
Chest wall edge of Bucky

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- Procedure 5 - Preparation for Small Focal Spot exposures
  1. Continue to run the normal Medical Application.
  2. Remove the Bucky from the image receptor.
  3. Remove the compression paddle if it has not already been removed.
  4. Install the magnification stand intended to provide 1.8X magnification.

  Note:
  When the magnification stand is installed, the collimator will automatically adjust to set the maximum field size (13 cm x 23 cm).
  5. Set the collimator for the 13 cm x 18 cm field size.
- Procedure 6 - Setup and exposures for MTF measurements of small focal spot width
  1. Position the acrylic block and the bar pattern that includes the 5 and 8 lp/mm groups on the breast support surface of the magnification stand as follows:

     If you are using a square acrylic block:

     Align one side of the block with the chest-wall surface of the magnification stand and center the block left-to-right.

     Position the bar pattern on the block so that the pattern is centered left-to-right, and so that the bars are parallel to the anode-cathode axis (perpendicular to the chest wall edge of the Bucky).

     Position the edge of the bar pattern 50 mm from the chest wall surface of the magnification stand (see *Illustration 7*).

     If you are using a trapezoidal acrylic block:

     Refer to *Illustration 6*.

     Align one of the non-parallel sides of the block with the chest wall surface of the magnification stand, and align the other non-parallel side with the lateral edge of the light field.

     Position the bar pattern on the block so that the pattern is centered left-to-right, and so that the bars are parallel to the anode-cathode axis (perpendicular to the chest wall edge of the Bucky).

     Orient the low frequency end of the bar pattern toward the side of block aligned with the lateral edge of the light field.

     Position the edge of the bar pattern 50 mm from the chest wall surface of the magnification stand (see *Illustration 7*).
  2. Select the manual exposure control mode and set the following parameters:
     Mo target; Mo filter; 30 kVp; 140 mAs.
  3. Select Left breast laterality and make an exposure.
  4. Select the manual exposure control mode and set the following parameters:
     Rh target; Rh filter; 30 kVp; 140 mAs.
  5. Select Left breast laterality and make an exposure.

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Illustration 6 MTF evaluation of small focal spot width - Positioning of trapezoidal acrylic block and bar pattern

View from focal spot

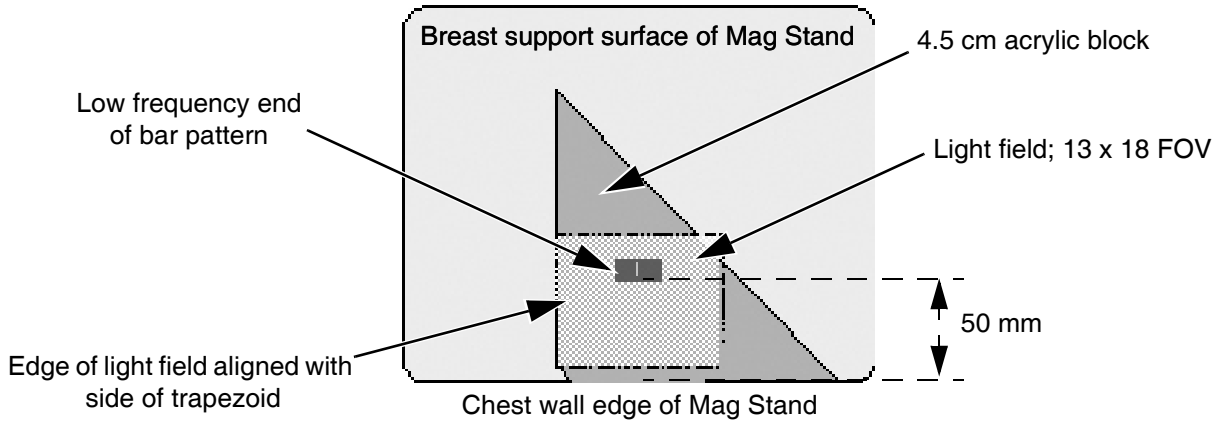
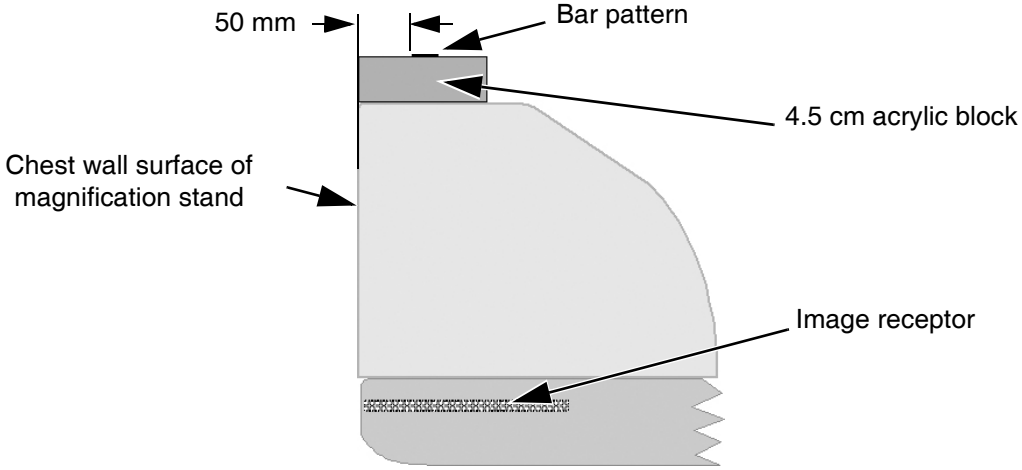

Breast support surface of Mag Stand
4.5 cm acrylic block
Low frequency end of bar pattern
Light field; 13 x 18 FOV
50 mm
Edge of light field aligned with side of trapezoid
Chest wall edge of Mag Stand

Illustration 7 MTF evaluation of small focal spot width and Length - Positioning of trapezoidal acrylic block and bar pattern

View from side of system



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- Procedure 7 - Setup and exposures for MTF measurements of small focal spot length
  1. Position the acrylic block and the bar pattern that includes the 5 and 8 lp/mm groups as described in Procedure 6, above.
  2. Position the bar pattern on the block so that the pattern is centered left-to-right, and so that the bars are now perpendicular to the anode-cathode axis (parallel to the chest wall edge of the Bucky).

     Orient the low frequency end of the bar pattern toward the chest wall edge of the image receptor (see *Illustration 8* below).

     Position the edge of the bar pattern 50 mm from the chest wall surface of the magnification stand (see *Illustration 7* above).

Note:

Because of the change in the effective length of the focal spot with position along the direction of the anode-cathode axis, the MTF measurement for the focal spot length is sensitive to the position of the bar pattern along that direction. For the small focal spot in the neighborhood of 50 mm from the chest wall surface of the magnification stand, the sub-system MTF has been observed to increase with increasing distance from the chest wall edge of the field at the rate of 0.0025/mm at 5 lp/mm and 0.0037/mm at 8 lp/mm. For consistent results, the bar pattern position must be carefully reproduced for each measurement.

3. Select the manual exposure control mode and set the following parameters:

   Mo target; Mo filter; 30 kVp; 140 mAs.
4. Select Left breast laterality and make an exposure.
5. Select the manual exposure control mode and set the following parameters:

   Rh target; Rh filter; 30 kVp; 140 mAs.
6. Select Left breast laterality and make an exposure.

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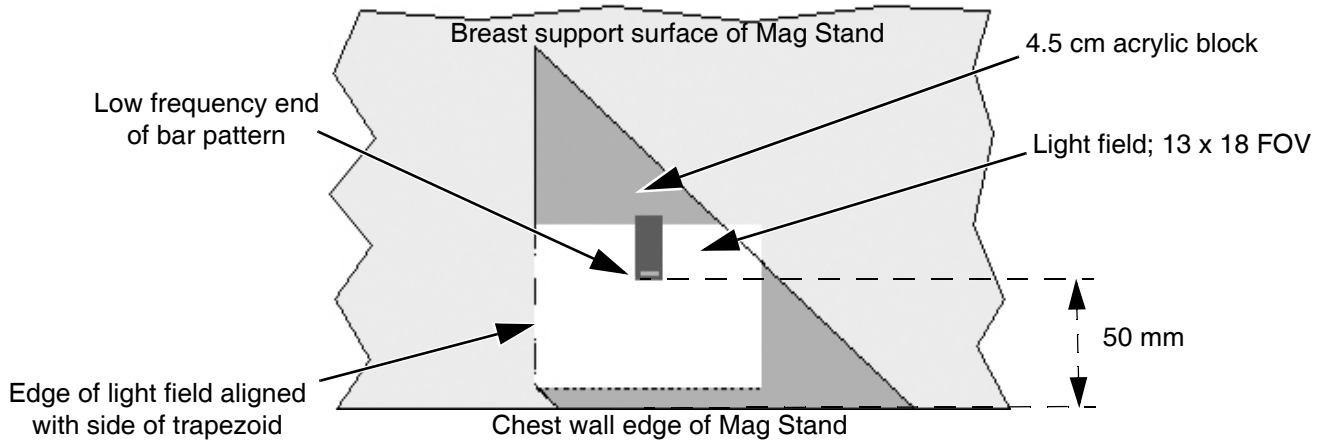
Illustration 8 MTF evaluation of small focal spot Length - Positioning of trapezoidal acrylic block and bar pattern

View from focal spot


Breast support surface of Mag Stand
4.5 cm acrylic block
Low frequency end of bar pattern
Light field; 13 x 18 FOV
50 mm
Edge of light field aligned with side of trapezoid
Chest wall edge of Mag Stand

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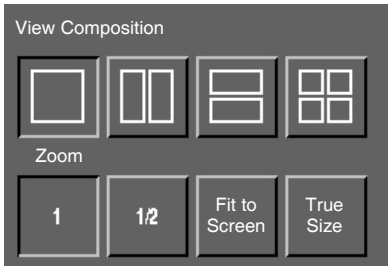
- Procedure 8 - Measurements on images acquired using the large focal spot



1. After completion of all Procedures 1 through 7, close the exam.
2. From the Browser, select the patient *Sub-System MTF*. Open the **Raw** images for exam review. **Do not make measurements on processed images.**
3. Select Zoom “1” in the *View Control* control panel of the Viewer window.
4. Adjust Window Width and Window Level for optimum visibility of the bar pattern image.
5. For each image acquired using the large focal spot, use the ellipse tool to make the measurements described below. Refer to *Illustration 9*.

   If the pattern is at a small angle, e.g., less than 10°, with respect to the pixel matrix, the ellipse may be rotated to improve alignment of the ROI with the pattern group (refer to Chapter 3 *Guidance* section *12-6 Ellipse Tool on page 108* for information on the use of the ellipse tool).

   If the angle of the pattern exceeds 10°, either repeat the acquisition of the bar pattern image or apply the frequency correction to the MTF as described in Chapter 3 *Guidance* section *12-5 Sensitivity of MTF Measurement to Bar Pattern Frequency Error on page 108*.

   a. Set the largest ROI containing only the 2.09 lp/mm pattern (see *Illustration 9*, ROI 1 and inset a). Adjust the size of the ROI to include as much of the 2.09 lp/mm pattern group as possible **without allowing the ROI to extend beyond the image of the pattern group**. See Chapter 3 *Guidance* section *12-2 Variation of MTF with ROI Width on page 107* regarding the effect of ROI size on the measurement.

   b. Record the ROI standard deviation, N(2.09).

   c. Set the largest ROI containing only the 3.93 p/mm pattern (see *Illustration 9*, ROI 2 and inset b). Adjust the size of the ROI to include as much of the 3.93 lp/mm pattern group as possible **without allowing the ROI to extend beyond the image of the pattern group**.

   d. Record the ROI standard deviation, N(3.93).

Note:

At the low-frequency end of the pattern there is a large area in which the highly attenuating pattern material has been removed. In the following this is referred to as “space” material. The nearby area of highly attenuating material is referred to as “bar” material.

e. Select an ROI of the default size and containing only “space” material (see *Illustration 9*, ROI 3). Record the ROI mean, S_s, and standard deviation, N_s.

f. Select an ROI of the default size and containing only “bar” material (see *Illustration 9*, ROI 4). Record the ROI mean, S_b, and standard deviation, N_b.

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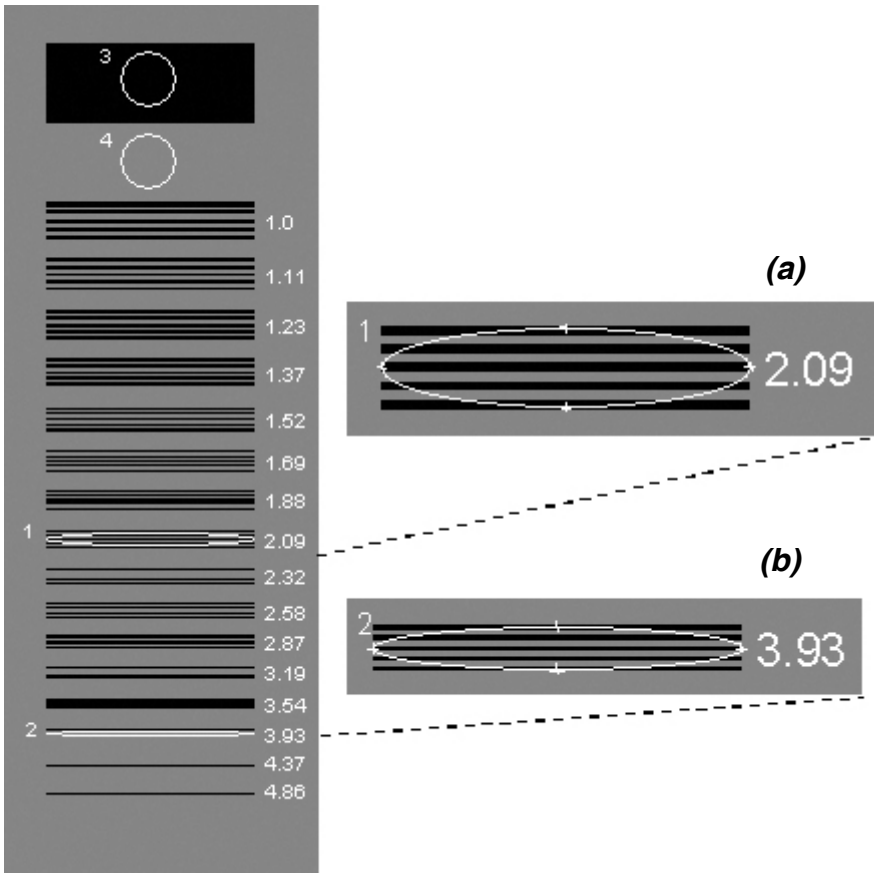
Note:

Analysis of the large focal spot sub-system MTF involves acquiring data for four cases - Mo track, focal spot length; Mo track, focal spot width; Rh track, focal spot length; and Rh track, focal spot width. All values of N(2.09), N(3.93), S_s, N_s, S_b, and N_b that will be used in the evaluation of a particular case must come from the image for that case.

If the operator uses a resolution test tool incorporating two orthogonal bar patterns, only two images need to be acquired, but each set of values N(2.09), N(3.93), S_s, N_s, S_b, and N_b must come from measurements on the same bar pattern. For example, values of S_s, N_s, S_b, and N_b acquired from the image of the bar pattern oriented to analyze the focal spot width must not be used in the analysis of the focal spot length unless the operator has previously verified that the two bar patterns produce the same degree of x-ray beam attenuation for the spectra used in this procedure.

Illustration 9 MTF analysis for the large focal spot



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- Procedure 9 - Measurements on images acquired using the small focal spot
  1. Measurements for the small focal spot are also made using Zoom "1" to view the **Raw** images from the patient *Sub-System MTF*. **Do not make measurements on processed images.**
  2. For each image acquired using the small focal spot, use the ellipse tool to make the measurements described below. Refer to *Illustration 10*.

     If the pattern is at a small angle, e.g., less than 10°, with respect to the pixel matrix, the ellipse may be rotated to improve alignment of the ROI with the pattern group (refer to Chapter 3 *Guidance* section *12-6 Ellipse Tool on page 108* for information on the use of the ellipse tool).

     If the angle of the pattern exceeds 10°, either repeat the acquisition of the bar pattern image or apply the frequency correction to the MTF as described in Chapter 3 *Guidance* section *12-5 Sensitivity of MTF Measurement to Bar Pattern Frequency Error on page 108*.

     a. Set the largest ROI containing only the 5 lp/mm pattern (see *Illustration 10*, ROI 1, inset a). Adjust the size of the ROI to include as much of the 5 lp/mm pattern group as possible **without allowing the ROI to extend beyond the image of the pattern group**. See Chapter 3 *Guidance* section *12-2 Variation of MTF with ROI Width on page 107* regarding the effect of ROI size on the measurement.

     b. Record the ROI standard deviation, N(5) in the table.

     c. Set the largest ROI containing only the 8 lp/mm pattern (see *Illustration 10*, ROI 2 and inset b). Adjust the size of the ROI to include as much of the 8 lp/mm pattern group as possible **without allowing the ROI to extend beyond the image of the pattern group**.

     d. Record the ROI standard deviation, N(8).

Note:

Test patterns used for evaluation of the small focal spot are of two general types - those with a high-attenuation substrate and those with a low-attenuation substrate. The key differences for this test are the locations of the “space” material and the “bar” material at the low-frequency end of the pattern. The regions of “space” material and “bar” material for each type of pattern are indicated in *Illustration 11*.

e. Select a region of interest containing only “space” material; select ROI 3a for a high-attenuation substrate pattern or select ROI 3b for a low-attenuation substrate pattern.
Record the ROI mean, S_s, and standard deviation, N_s.

f. Select an ROI containing only “bar” material; select ROI 4a for a high-attenuation substrate pattern or select ROI 4b for a low-attenuation substrate pattern.
Record the ROI mean, S_b, and standard deviation, N_b.

Note:

The size and positioning of the ROIs used for sampling the bar and space material will depend on the characteristics of the particular bar pattern used for the test. Set two ROIs that are substantially the same shape and positioned at the same end of the bar pattern. Set the area of each ROI within ± 25% of the area of the ROI used to measure the standard deviation in the 8 lp/mm pattern.

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Note:

Analysis of the small focal spot sub-system MTF involves acquiring data for four cases - Mo track, focal spot length; Mo track, focal spot width; Rh track, focal spot length; and Rh track, focal spot width. All values of **N(5), N(8), S_s, N_s, S_b, and N_b** that will be used in the evaluation od a particular case must come from the image for that case.

If the operator uses a resolution test tool incorporating two orthogonal bar patterns, only two images need to be acquired, but each set of values N(5), N(8), S_s, N_s, S_b, and N_b must come from measurements on the same bar pattern. For example, values of S_s, N_s, S_b, and N_b acquired from the image of the bar pattern oriented to analyze the focal spot width must not be used in the analysis of the focal spot length unless the operator has previously verified that the two bar patterns produce the same degree of x-ray beam attenuation for the spectra used in this procedure.

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Illustration 10 MTF analysis for the small focal spot

This illustration shows the image of a pattern made from a high-attenuation substrate.

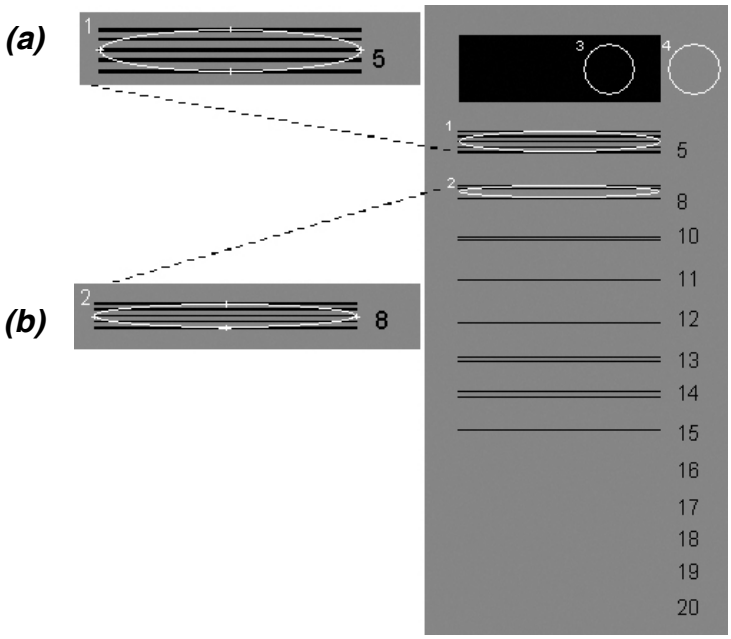
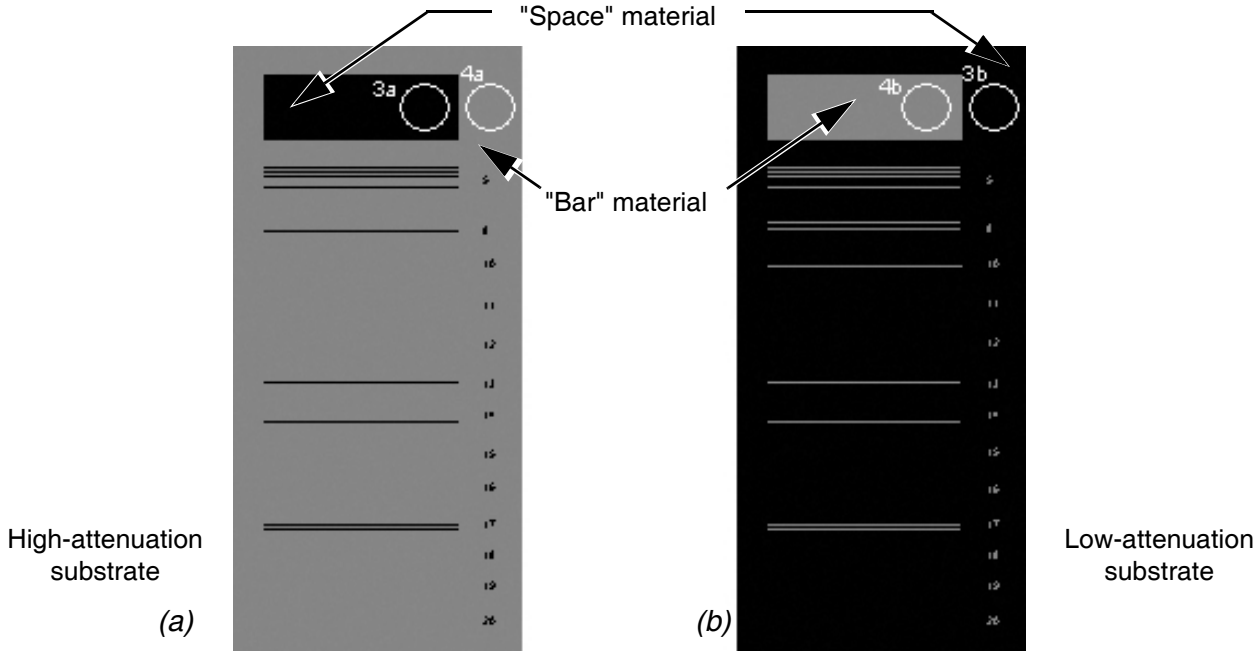


Illustration 11 Images of High and Low attenuation test patterns

This illustration shows images of test patterns made from a high-attenuation substrate (left), e.g., gold foil, and from a low-attenuation substrate (right), e.g., plastic.



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- Procedure 10 - Analysis of MTF measurements
  1. For each case (each focal spot size, each anode track, and each axis), use the following equations to estimate the MTF M(f) for the two frequency points :

$$M_0 = \frac{\sqrt{2}}{\pi}\left(S_s - S_b\right) = 0.45\left(S_s - S_b\right) \qquad N^2 = \frac{N_s^2 + N_b^2}{2} \qquad M(f) = \frac{\sqrt{N^2(f) - N^2}}{M_0}$$

     where:

     S_s = the mean value in a region of interest (ROI) including only “space” material,

     S_b = the mean value in an ROI including only “bar” material,

     N_s = the standard deviation in an ROI including only “space” material,

     N_b = the standard deviation in an ROI including only “bar” material,

     N(f) = the standard deviation in an ROI including the bar pattern group of frequency f, and

     M(f) = the MTF at frequency f.

     f = 2.09 and 3.93 lp/mm for the large focal spot.

     f = 5 and 8 lp/mm for the small focal spot.

     See Chapter 3 *Guidance* section *12-7 References for MTF Calculations on page 108* for reference material on these calculations.
  2. If necessary, correct the MTF for bar pattern frequency inaccuracy. See Chapter 3 *Guidance* section *12-5 Sensitivity of MTF Measurement to Bar Pattern Frequency Error on page 108* regarding sensitivity of the MTF to bar pattern frequency error.
  3. Record the results in *Chart 2A - Sub-System MTF Measurement on page 89*.
  4. Close the Viewer window.

Note:

The MTF measured from the *Raw* image may have a magnitude similar to, although not the same as, the MTF measured from a *Processed* image. If the magnitude of the MTF changes suddenly, check to make sure that the analysis is being made from the *Raw* image. If the measurement is made from a *Processed* image, the calculations described above will produce negative MTF values. This is because in the *Processed* image S_s is less than S_b. If the MTF is negative, or S_s is observed to be less than S_b, then the wrong image is being used for the MTF measurement. Select the *Raw* image.

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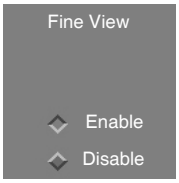
- Procedure 11 - Restore FineView Setting
  If FineView was enabled before starting this test, re-enable FineView:

  1. From the Browser click the **Tools menu** button (near the top right of the Browser screen) to display the utilities menu.
  2. Select **Medical Application preferences** from the drop-down menu.
  3. In the *Medical Application preferences* window, click on the button labeled *Fine View*

     or *Image Process*

     .
  4. Enable FineView: 

  5. Record the current FineView status in *Chart 2A - Sub-System MTF Measurement on page 89*.
     - Click **Save**.

     - Click **Close**.

- Action Limit:
  The MTF values obtained in the test must exceed the Action Limits specified in the following table.

		Large Focal Spot		Small Focal Spot	
Track	**Axis**	**Freq. (lp/mm)**	**Action Limit**	**Freq. (lp/mm)**	**Action Limit**
Mo	Width	2.09	0.58	5	0.34
Rh	Width	2.09	0.58	5	0.34
Mo	Length	2.09	0.58	5	0.34
Rh	Length	2.09	0.58	5	0.34
Mo	Width	3.93	0.26	8	0.11
Rh	Width	3.93	0.26	8	0.11
Mo	Length	3.93	0.26	8	0.11
Rh	Length	3.93	0.26	8	0.11

- Use of Test Results:
  If the above specifications are not met, the source of the problem must be identified and corrective action taken before any further mammographic images are acquired using the Senographe DS system that failed. Refer to Chapter 3 *Guidance* section *12-8 Actions to be taken if specifications are not met on page 109* for additional information.

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Chart 2A - Sub-System MTF Measurement

Date: . . . . . .

FineView status at the start of the measurement (circle one) **Disabled** **Enabled**

FineView status at the end of the measurement (circle one) **Disabled** **Enabled**

Be sure to return the FineView selection to the one normally chosen during clinical use.

Large Focal Spot MTF Measurements:

Track	Axis	N(2.09)	N(3.93)	S_s	Ns	S_b	N_b	M(2.09)	M(3.93)
Mo	Width								
Rh	Width								
Mo	Length								
Rh	Length								

Small Focal Spot MTF Measurements:

Track	Axis	N(5)	N(8)	S_s	Ns	S_b	N_b	M(5)	M(8)
Mo	Width								
Rh	Width								
Mo	Length								
Rh	Length								

$$M_0 = \frac{\sqrt{2}}{\pi}\left(S_s - S_b\right) = 0.45\left(S_s - S_b\right) \qquad N^2 = \frac{N_s^2 + N_b^2}{2} \qquad M(f) = \frac{\sqrt{N^2(f) - N^2}}{M_0}$$

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- Action Limit:
  The MTF values obtained in the test must exceed the Action Limits specified in the following table.

		Large Focal Spot		Small Focal Spot	
Track	**Axis**	**Freq. (lp/mm)**	**Action Limit**	**Freq. (lp/mm)**	**Action Limit**
Mo	Width	2.09	0.58	5	0.34
Rh	Width	2.09	0.58	5	0.34
Mo	Length	2.09	0.58	5	0.34
Rh	Length	2.09	0.58	5	0.34
Mo	Width	3.93	0.26	8	0.11
Rh	Width	3.93	0.26	8	0.11
Mo	Length	3.93	0.26	8	0.11
Rh	Length	3.93	0.26	8	0.11

- Use of Test Results:
  If the above specifications are not met, the source of the problem must be identified and corrective action taken before any further mammographic images are acquired using the Senographe DS system that failed. Refer to Chapter 3 *Guidance* section *12-8 Actions to be taken if specifications are not met on page 109* for additional information.

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Job Card VF-P03 - Breast Entrance Exposure, Average Glandular Dose and Reproducibility

- Objective:
  To measure the typical entrance exposure for an average patient (approximately 4.2-cm compressed breast thickness-50% adipose, 50% glandular composition), to calculate the associated average glandular dose, and to assess short-term exposure reproducibility.
- Required Test Equipment:
  - Ionization chamber and electrometer calibrated at mammographic X-ray beam energies (calibration factor constant to within ± 1% over the HVL range from 0.2 to 0.5 mm Al).
  - Mammographic phantom (equivalent to approximately 4.2 cm compressed breast tissue 50/50 composition at mammographic energies). Acceptable phantoms are listed in Chapter 3 *Guidance* section *13 Breast Entrance Exposure, Average Glandular Dose, and Reproducibility on page 110*.

Note:
If the phantom has thumbscrews that extend above the surface of the phantom or an acrylic disk attached to the surface of the phantom, these screws and disk must be removed before acquiring the image of the phantom. The phantom surfaces that contact the breast support and the compression paddle must both be flat.

- Procedure:
  1. Prepare the mammographic imaging system as follows:
     - operation in the contact geometry with the grid installed,
     - 19 cm x 23 cm field of view selected.

     Record these conditions on the data form.
  2. Position the mammographic phantom on the image receptor assembly at the position which would normally be occupied by the patient's breast (laterally centered in the X-ray field with one edge coincident with the chest wall edge of the image receptor assembly).

Note:
The phantom must be rotated 180° from its normal orientation. Position the wide edge of the frame surrounding the wax insert away from the chest wall edge of the image receptor.

  3. Position the ionization chamber in the X-ray field with its center approximately 4 cm in from the chest wall edge of the image receptor and with the top surface of the chamber near the top surface of the phantom. The interior edge of the chamber must be no more than 3.5 cm from the lateral edge of the X-ray field as indicated by the light localizer.
     See *Illustration 1* and *Illustration 2*.

Note:
If AOP is used for establishing the entrance exposure, it is important that the parameter selection be based only on the phantom and not the ion chamber. Hence, the ion chamber must be positioned outside the sensing area used by AOP to avoid having the parameter selection determined by any highly attenuating elements of the chamber. The ion chamber is first used to monitor output reproducibility and not the entrance exposure; hence its exact position in the field is not critical.

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Illustration 1 Set up to monitor output reproducibility in AOP mode (top view)

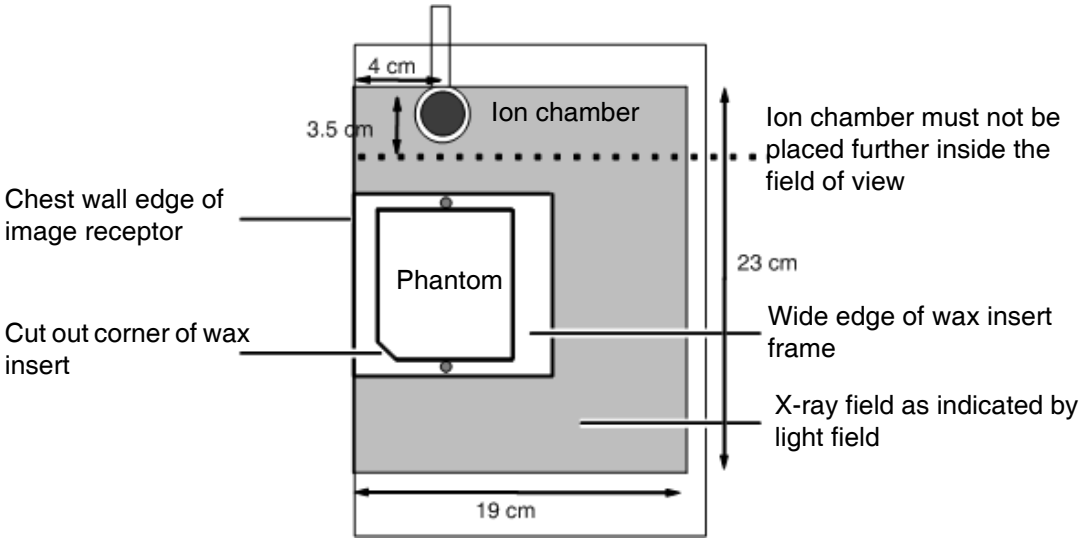
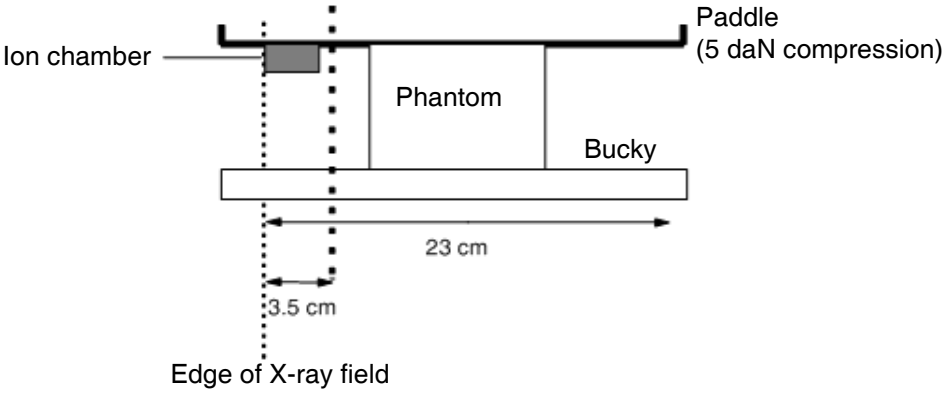

4 cm
3.5 cm
Ion chamber
Ion chamber must not be placed further inside the field of view
Chest wall edge of image receptor
Phantom
23 cm
Cut out corner of wax insert
Wide edge of wax insert frame
X-ray field as indicated by light field
19 cm

Illustration 2 Set up to monitor output reproducibility in AOP mode (front view)



4. Secure the chamber in position and do not change the position of the chamber during the following measurements.

Note:

Mammographic imaging systems have a significant X-ray intensity gradient in the X-ray field along the anode-cathode direction. Maintaining a constant chamber position during measurements is critical. When measurements are to be compared with others made previously, it is also critical that the original measurement position be re-established as closely as possible.

5. Position the compression device in the X-ray beam, just in contact with the phantom and chamber.

Note:

If measurements will be done using AOP, apply a compression force of 5 daN to activate the algorithm. The compressed breast thickness is used by the AOP algorithm to determine the imaging parameters. Therefore, it is important to position the phantom and apply the compression force consistently for each measurement since variations in paddle deflection may be interpreted as variations in compressed breast thickness leading to inconsistency in parameter selection.

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6. Select the image acquisition mode, i.e., AOP or Manual, most commonly used clinically to image the standard breast. For AOP mode select the clinically used setting of CNT, STD, or DOSE. For Manual mode select the clinically used settings of kVp, anode track, X-ray beam filter, and mAs. Record the settings on the data form.

Note:

GE recommends that Standard (STD) and Dose (DOSE) mode be used for routine mammography.

Contrast (CNT) mode of the Senographe DS delivers more dose than Standard (STD) and Dose (DOSE) modes.

GE recommends that Contrast (CNT) mode be used only after consultation with an interpreting physician or radiologist.

7. Make an exposure.
8. Record the mAs and the reading of the ion chamber. For AOP mode also record the selections of kVp, anode track, and filter.
9. Make additional exposures and record the results until a total of four exposures have been recorded.
10. If necessary, raise the compression paddle, then position the reference line of the ion chamber level with the top surface of the phantom.
11. Remove the phantom and position the ion chamber centered left-to-right and 4 cm from the chest wall edge of the image receptor.
12. Position the compression paddle to just contact the ionization chamber.
13. Select Manual mode and set the kVp, anode track, and filter used when exposing the phantom. Select an mAs as close as possible to the mAs used when exposing the phantom.
14. Make an exposure and record the ion chamber reading.
15. Compute the averages and standard deviations for mAs and exposure for the four exposures acquired with identical technique settings. Record the values. Determine the coefficients of variation (standard deviation divided by the mean).
16. Correct the ion chamber reading from Step *14.* to the value appropriate for Step *7.* using the ratio of the mAs recorded in Step *8.* to the mAs selected in Step *13.* Using the corrected ion chamber reading, calculate the average glandular dose using generally accepted methods for mammography quality control. See Chapter 3 *Guidance* section *13 Breast Entrance Exposure, Average Glandular Dose, and Reproducibility on page 110*.

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- Action Limit - mAs and Air Kerma Reproducibility:
  The maximum acceptable coefficient of variation for both mAs and air kerma in the reproducibility test is 0.05.
- Use of Test Results:
  If these conditions are not met, the source of the problem must be identified, and corrective actions taken, within 30 days of the test date.
- Action Limit - Mean Glandular Dose:
  The mean glandular dose to the Standard breast must not exceed 3 mGy (0.3 rad) per view.
- Use of Test Results:
  If this condition is not met, the source of the problem must be identified, and corrective actions taken, before any further mammographic images are acquired using the Senographe DS FFDM system that failed. See Chapter 3 *Guidance* section *13 Breast Entrance Exposure, Average Glandular Dose, and Reproducibility on page 110*.

The applicable MQSA Quality Mammography Standards are:

900.12(e)(5)(v)
Breast entrance air kerma and AEC reproducibility.
The coefficient of variation for both air kerma and mAs shall not exceed 0.05.
900.12(e)(5)(vi)
Dosimetry
The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

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Chart 3 - Breast Entrance Exposure, Average Glandular Dose and Reproducibility (1/2)

Dosimetry system used . . . . . .
Field size . . . . . .
Phantom ID . . . . . .

Imaging Parameters and Reproducibility

Breast thickness	**4.2 cm**			
Phantom				
Exposure Control Mode (AOP, Man.)				
Nominal kVp setting				
Target/Filter				
mAs setting				
Measured HVL (mm Al)				

Exposure Readings	**R**	**mAs**	**R**	**mAs**	**R**	**mAs**	**R**	**mAs**
Exposure #1								
Exposure #2								
Exposure #3								
Exposure #4								
Mean Values								
Standard Deviations (SD)								
Coefficients of Variation (CV)								

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Chart 3 - Breast Entrance Exposure, Average Glandular Dose and Reproducibility (2/2)

Dosimetry

Ion Chamber Reading				
mAs				
Energy & mAs Corrected Exposure				
Dose Conversion Factor (mrad/R)				
Computed Avg. Glandular Dose (mrad)				

Action Limit:
The Coefficient of Variation for both air kerma and mAs must not exceed 0.05.
Use of Test Results: If these conditions are not met, the source of the problem must be identified, and corrective action taken, within 30 days of the test date.
Action Limit:
The average glandular dose must not exceed 3 mGy (0.3 rad) for a 4.2 cm effective breast thickness.
Use of Test Results:
If this condition is not met, the source of the problem must be identified, and corrective action, taken before further mammographic images are acquired using the Senographe DS FFDM system that failed.

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Job Card VF-P04 - Artifact Evaluation and Flat Field Uniformity

- Objective:

  To assess the degree and source of artifacts visualized in full field digital mammograms or phantom images.

  To assure that the flat field image is uniform.
- Required Test Equipment:
  - A 25 mm thick uniform sheet of acrylic (PMMA) that is clean and free from defects. The acrylic sheet must be sufficiently large to cover the entire image receptor.

Note:

To allow for temperature stabilization of the detector, the system must be powered on for at least 10 minutes before performing any measurements related to detector image quality. If any test is not passed after allowing a 10-minute warm-up period, see Chapter 3 *Guidance* section *14 Artifact Evaluation and Flat Field Uniformity on page 110*.

- Procedure:
  1. Use technique factors normally used clinically, choosing the lowest kVp setting (to be most sensitive to artifacts). Record the technique factors on the data form.
  2. Install the anti-scatter grid. Place the attenuator sheet on top of the image receptor. Set collimation that permits irradiation of the entire image receptor.
  3. Make an exposure.
  4. Repeat steps 1 through 3 for the Mo/Mo, Mo/Rh, and Rh/Rh target/filter combinations.
  5. If the small focal spot is used clinically.
     a. Remove the attenuator sheet and the anti-scatter grid.
     b. Install the magnification stand to provide a clinically used magnification selection.
     c. Place the attenuator sheet on the breast support surface of the magnification stand.
     d. Set the collimation to the largest field of view.
     e. Acquire images for the Mo/Mo, Mo/Rh, and Rh/Rh target/filter combinations.
  6. Select the **Raw** image for review.
  7. Set the window width in the range of about 400 to 450 and the window level to a setting that allows visualization of artifacts if present. Examine the image for gridlines, plus or minus signal variations, streaking in the horizontal or vertical directions, residual images left over from repeated test or clinical exposures, acrylic sheet artifacts, or bad pixels.
  8. With a window width in the range of about 400 to 450, examine the image for flat field uniformity.
  9. Review the images for the three target/filter combinations.
  10. Review at least one of the images on all display devices, e.g., AWS, laser printer.
  11. If any artifacts or non-uniformities are present, rotate the acrylic sheet 90^{o} and repeat the exposure and acquisition procedure.

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12. If any artifacts or non-uniformities keep a fixed orientation relative to the image receptor in both images and are expected to simulate or mask visualization of breast structures or breast pathology, determine whether the artifact or non-uniformity is due to the detector or the display.
    a. If the artifact or non-uniformity is present on all monitors or the artifact moves as the image is moved using the Roam tool, it is most likely associated with the image acquisition system.
    b. If the artifact appears only on one monitor, clean the faceplate of the display (See Chapter 1 *QC Tests for the Radiologic Technologist*, section *3 Monitor Cleaning on page 15*).
    c. If the artifact appears only on printed images, follow the directions provided by the manufacturer of the printer.
13. If any corrective actions were taken, repeat the artifact evaluation and review the image.

- Action Limit:

  There must be no artifact or non-uniformity present which might mimic or obscure clinical information.
- Use of Test Results:

  If an artifact or non-uniformity is present and is expected to mimic or obscure clinical information, the source of the problem must be identified and corrective actions taken within 30 days of the test date. See Chapter 3 *Guidance* section *14 Artifact Evaluation and Flat Field Uniformity on page 110*.

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Chart 4 - Artifact Evaluation and Flat Field Uniformity

Type of Attenuator . . . . . .
Thickness of Attenuator . . . . . .
kVp setting . . . . . .
mAs setting . . . . . .
Image Receptor size . . . . . .
Patient ID # . . . . . .
Field size . . . . . .

	Mo/Mo	Mo/Rh	Rh/Rh	Mo/Mo	Mo/Rh	Rh/Rh
Focal Spot						
Magnification						
kVp						
mAs						
Artifact visible?						
Flat Field Non-Uniformity						
Equipment Artifact						
Detector						
Grid						
Attenuator Defect						
Other						
Description of Artifacts:						

Use of Test results:
If an artifact or non-uniformity is present, and is expected to mimic or obscure clinical information, the source of the problem must be identified and corrective actions taken within 30 days of the test date.

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Chapter 3 Guidance

United States regulations consider the manufacturer's QC Test procedures as a requirement for compliance with the MQSA regulations. This Guidance section is not considered an element of those regulations. It is intended to provide guidance to mammography facilities and their personnel. It represents the equipment manufacturer's current thinking on appropriate procedures for conducting the QC tests. Procedures described in guidance represent supplementary information on acceptable ways of doing a test but, unlike regulations, do not bind the facility to using that way only. An alternative procedure may be used if such a procedure satisfies the requirements of the applicable statute, regulations, or both. Mandatory language, such as "shall," "must", and "require", is used when referring to statutory or regulatory requirements. Non-mandatory language, such as "should", "may", "can" and "recommend" is used when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations.

Under its own authority, a state may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility may want to check with the state or local authorities regarding their requirements. Tests may be performed more frequently than specified in the QC tests if required by local regulations or hospital requirements.

QC tests may be used as a check for correct operation, for example, after a change of operating parameters.

The following sections provide specific guidance for sections in the QC tests.

1 Wet Chemistry Film Processing

If the film from the printer requires wet chemistry processing and if specific instructions are not provided by the manufacturer of the printer, it is recommended that the facility follow accepted procedures for the QC of darkroom cleanliness, darkroom fog, and analysis of fixer retention such as those included in the *Mammography Quality Control Manual* published by the American College of Radiology.

2 Flat Field Test

If the system fails any of the elements of the Flat Field test, you should ensure that all test conditions are met and then repeat the test. If the detector has been allowed to warm up for at least 10 minutes, but less than 30 minutes, allow an additional 20 minutes for the detector to warm up (total of 30 minutes) then repeat the test. If the system still fails, it is recommended that you contact your GE Medical Systems Service Engineer.

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3 Phantom Image Quality Test

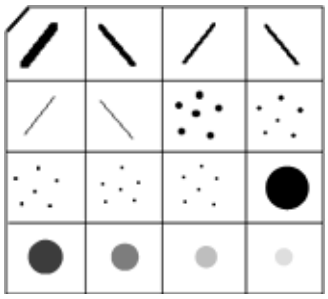
3-1 Quality Control Phantom

The equipment required is an FDA-approved phantom.

Following is a list of suitable mammographic phantoms made according to ACR specifications:

- Radiation Measurements, Inc., Model 156.
- Fluke Biomedical (Nuclear Associates), Model 18-220.
- Computerized Imaging Reference Systems, Model 15.

The phantom is an acrylic block containing 16 cells. Each cell simulates an anatomical structure which may be found in breast tissue.



Starting from the top left hand corner, as shown in the illustration, the cells are of three types:

- **Fibers:** Six cells represent fibrous structures; they contain fibers with cross-sections from 1.56 mm to 0.40 mm.
- **Speck Groups:** Five cells represent micro-calcifications, with diameters from 0.54 mm to 0.16 mm.
- **Masses:** Five cells represent tumors or masses, with thicknesses from 2 mm to 0.25 mm.

3-2 Scoring the Phantom Image

A recommended method of scoring the phantom image, including deduction of the score for artifacts, is included in the *Mammography Quality Control Manual* published by the American College of Radiology.

3-3 Failure of Phantom Image Quality Test

If the system fails the Phantom Image Quality Test, you should ensure that all test conditions are met and then repeat the test. If the detector has been allowed to warm up for at least 10 minutes, but less than 30 minutes, allow an additional 20 minutes for the detector to warm up (total of 30 minutes) then repeat the test. Situations have occurred in which inability to achieve a passing score has been attributable to artifacts in the phantom or defects in the test objects. If this is a possibility, try using a different phantom and repeat the test. If the system still fails, it is recommended that you contact your GE Medical Systems Service Engineer.

3-4 Appearance of Collimator Blades in Image

If collimator blades are visible in the image, it is recommended that you contact your GE Medical Systems Service Engineer.

3-5 Failure of Phantom Image Quality Test for Printer

If the printer fails the Phantom Image Quality Test, you should ensure that all test conditions are met and then repeat the test. If the system still fails, it is recommended that you consult the documentation provided with the printer for information on quality control and troubleshooting procedures.

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4 CNR and MTF Measurement

4-1 Failure of MTF Measurement Test

If the system fails the MTF Measurement Test, you should ensure that all test conditions are met and then repeat the test. If the detector has been allowed to warm up for at least 10 minutes, but less than 30 minutes, allow an additional 20 minutes for the detector to warm up (total of 30 minutes) then repeat the test. If the system still fails, it is recommended that you contact your GE Medical Systems Service Engineer.

4-2 Failure of Change in CNR Test

If the system fails the Change in CNR Test, and the detector has been allowed to warm up for at least 10 minutes, but less than 30 minutes, allow an additional 20 minutes for the detector to warm up (total of 30 minutes) then repeat the test. If the system still fails, it is recommended that you contact your GE Medical Systems Service Engineer.

5 AOP Mode and SNR Check

A flow chart illustrating how to access the menu for adjusting the maximum compression force is shown in the Senographe DS Acquisition system Operator Manual. Press the SET UP menu key , then the button under “Medical”, and then the button under “Force”. Press the button under the “+” sign to increase the compression force; press the button under the “-” sign to decrease the force. After achieving the desired maximum force value, press the button under “Valid”, then press the SET UP menu key until the Applications menu returns and the lamp under the button goes out.

For the AOP Mode Check, if the test passes enter the mAs observed for each object thickness. If the test fails, enter “F/n” where “n” refers to the number of a note. Use the same number to record a note below the table to state the nature of the failure and what was done to correct it.

If the system fails the AOP Mode Check or the SNR Check, you should ensure that all test conditions are met and then repeat the test. If the detector has been allowed to warm up for at least 10 minutes, but less than 30 minutes, allow an additional 20 minutes for the detector to warm up (total of 30 minutes) then repeat the test. If the system still fails, it is recommended that you contact your GE Medical Systems Service Engineer.

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6 Repeat Analysis Check

Depending on your version of the Senographe DS, the method used for Repeat and Reject analysis can be manual or automated, as described in Chapter 1 *QC Tests for the Radiologic Technologist* section *9 Repeat Analysis Check on page 27*.

6-1 Manual Method

The total number of exposures taken during the analysis period can be estimated from the exposure counter available on the Control Console. When the setup button is pressed, a count of the number of exposures since the last software installation appears in the upper right hand corner of the control console display. This value can be recorded at the beginning and end of the analysis period and the difference in the two values is the number of exposures made during this time. If the value of the counter is also monitored during QC testing and physicist surveys, the exposure count can be corrected for the non-clinical exposures. The counter should also be monitored before and after any servicing of the unit in case the service work results in the resetting of the counter.

6-2 Automated Method

To use the automated method of Repeat and Reject Analysis (when available), each image must be qualified during the examination as *Accepted*, *Rejected*, or *Repeated*, as described in the Operator Manual.

6-3 Record of loss of data

The data for the automated repeat analysis are stored in a computer in the acquisition workstation (AWS). In the event of an AWS hardware failure, there is some risk that these data will be lost. That is why periodic data backup is included in the automated repeat analysis procedure (refer to section *9-3 Repeat Analysis - Database backup on page 32*).

In the event of a system failure that results in the loss of information from your repeat analysis database, you should record the occurrence and cause of the data loss in the QC log to provide documentation on why an analysis may not have been completed for a particular quarter. You should also request a copy of the service record prepared by the Field Service Engineer indicating the nature of the failure and the loss of information in the database.

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7 Compression Force Test

In addition to the testing interval specified in the test procedure, the compression force test should also be performed when reduced compression is suspected.

The procedures for the compression force test given in the *Mammography Quality Control Manual* published by the American College of Radiology are recommended.

If the system fails the Compression Force Test, you should ensure that all test conditions are met and then repeat the test. If the system still fails, it is recommended that you contact your GE Medical Systems Service Engineer.

8 Visual, Monitor, and Filming Checks

If a malfunction of the Senographe DS is observed during the Visual Check, it is recommended that you contact your GE Medical Systems Service Engineer.

8-1 Viewboxes and Viewing Conditions

Recommended methods for assessing viewing conditions and caring for viewboxes are included in the *Mammography Quality Control Manual* published by the American College of Radiology.

8-2 Monitor Cleaning

If a monitor cannot be satisfactorily cleaned, it is recommended that you contact your GE Medical Systems Service Engineer.

8-3 Printer QC

For information on the recommended QC procedures for the printer, the user should refer to the Printer Operator's Manual or ancillary documentation provided by the manufacturer of the printer.

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9 Annual Physicist Checks

9-1 kVp Accuracy and Reproducibility

Acceptable procedures for the measurement of kVp accuracy and reproducibility can be found in the *Mammography Quality Control Manual* published by the American College of Radiology.

Note:

If the action limits for kVp accuracy or coefficient of variation are exceeded using the results of four (4) exposures, then make six (6) additional readings and recalculate using all 10 readings. If the results calculated using all ten (10) measurements exceed the action limits, the source of the problem must be identified and corrective action taken within 30 days of the test date. It is recommended that you contact your service engineer.

9-2 Beam Quality Assessment

Acceptable procedures for the measurement of half-value layer can be found in the *Mammography Quality Control Manual* published by the American College of Radiology. The thicknesses of the aluminum filters should be known to within ± 1%. The use of type 1100 aluminum alloy for HVL measurement can give (depending on specific samples) HVL values up to 7.5% lower than those measured using pure aluminum. If type 1100 aluminum is used, results should be corrected to agree with those obtained using pure aluminum.

9-3 Mammography Unit Assembly Evaluation and Radiation Output

The mammographic unit assembly evaluation and measurement of radiation output, may be performed as described in the *Mammography Quality Control Manual* published by the American College of Radiology.

10 Collimation Assessment

If the system does not pass the collimation assessment test, you should ensure that all test conditions are met and then repeat the test. If the system still fails, it is recommended that you contact your GE Medical Systems Service Engineer.

11 Evaluation of FocalJ Spot Performance

It is important that the test pattern be positioned in a reproducible manner. A test stand may be helpful.

If the required specifications are not met, remove the compression paddle if it was included in the original setup and retest with the same geometry. If the results are still below the specifications, a more detailed investigation of the reason should be made. For example, make a measurement of the focal spot dimensions (slit camera measurement) or limiting resolution (star pattern measurement). Information on additional procedures to apply to the evaluation of the focal spot performance can be found in the *Mammography Quality Control Manual* published by the American College of Radiology.

If the system does not pass the Evaluation of Focal Spot Performance test, it is recommended that you contact your GE Medical Systems Service Engineer.

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12 Sub-System MTF Measurement

12-1 Suitable Bar Patterns

Suitable bar patterns for performing the Sub-System MTF measurement at 2.09 and 3.93 lp/mm include the Fluke Biomedical Models 07-501-1000 and 07-501-2000 and the Gammex/RMI Model MA0436.

Suitable bar patterns for performing the Sub-System MTF measurement at 5 and 8 lp/mm include the Fluke Biomedical Model 07-555, the Gammex/RMI Model MA0647, and the Computerized Imaging Reference Systems Model 016A.

12-2 Variation of MTF with ROI Width

Theoretical analysis of the effect of the ROI width on the MTF measurement suggests that it is better to err on the side of setting the width too small rather than too large. It is expected that when the ROI width exceeds the pattern group width, the standard deviation in the ROI, and consequently the MTF, will increase with further increases of the ROI width.

To determine an appropriate ROI width to use, the physicist can vary the width and observe the ROI standard deviation. If the ROI width is too large, the standard deviation in the ROI will tend to increase with further increases of the ROI width. When the ROI is inside the pattern group image, the standard deviation will fluctuate as the ROI width is changed, but it is not expected to change consistently in one direction as the ROI width is changed in one direction (wider or narrower).

12-3 Use of Dual-Orthogonal Test Patterns for the MTF Measurement

Certain resolution test devices contain two bar patterns disposed at right angles to each other. Two concerns regarding these patterns have been identified - the angle between the two patterns and the ability to position the patterns according to the requirements of this procedure.

In some cases the angle between the two patterns is apparent to be other than 90°. The bar pattern frequency along a particular axis varies as the cosine of the angle between the axis and the normal to the bars of the frequency pattern group. At an angle of 10°, the frequency error would be about 1.5%. Based on the sensitivity information below, that would change the sub-system MTF for the magnification configuration by less than 0.01, which is not significant.

An approach one could take when using a test device with non-orthogonal patterns is to “split the difference” of the error. For example, if the angle between the patterns is 80° instead of 90°, the physicist could rotate the pattern a few degrees so that both patterns were about 5° off the intended axis. At 5° the frequency error is about 0.4%, resulting in an MTF error of not more than 0.0025.

The other concern regarding the dual pattern devices is the ability to position the patterns according to the requirements of the procedure. Two of the positioning requirements are:

- Position the edge of the pattern at the specified distance from the chest wall edge of the image receptor or magnification stand.
- When evaluating the focal spot length, position the lowest frequency pattern group toward the chest wall edge of the image receptor.

Due to the way that the two patterns are disposed in some versions of these devices, it is not possible to meet these requirements simultaneously for both patterns. Of course, the device may be separately positioned to meet the requirements for each measurement. But, if a single image is being used to evaluate the MTF along two axes, the physicist should take care to ensure that the positioning of the bar patterns meets the requirements of the procedure.

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12-4 Bar Pattern Frequency Inaccuracy

Inaccuracy of the pattern group frequencies can lead to errors in the MTF estimate. Errors of 0.5 lp/mm have been observed which can (based on estimates as suggested below) lead to errors in the MTF of about 0.06 at 5 lp/mm and 0.04 at 8 lp/mm. It is recommended that the physicist measure the frequencies of the pattern groups to establish their accuracy and correct the MTF measurements as necessary.

12-5 Sensitivity of MTF Measurement to Bar Pattern Frequency Error

The following table shows values of the increase in sub-system MTF associated with a 1% decrease in the spatial frequency at the spatial frequency points used for the test. These values can be used to estimate the effect on the MTF due to errors not exceeding ± 10% in the spatial frequency of the bar pattern used for the evaluation.

		Large Focal Spot		Small Focal Spot	
Track	**Axis**	**Freq. (lp/mm)**	**Δ MTF**	**Freq. (lp/mm)**	**Δ MTF**
Mo	Width	2.09	0.0035	5	0.0055
Rh	Width	2.09	0.0035	5	0.0056
Mo	Length	2.09	0.0035	5	0.0054
Rh	Length	2.09	0.0034	5	0.0052
Mo	Width	3.93	0.0057	8	0.0057
Rh	Width	3.93	0.0057	8	0.0056
Mo	Length	3.93	0.0057	8	0.0058
Rh	Length	3.93	0.0057	8	0.0059

12-6 Ellipse Tool

Information on the use of the ellipse tool may be found in the *Viewer* chapter of the Operator Manual for the Senographe DS Acquisition System.

12-7 References for MTF Calculations

The method of determining MTF based on calculations of means and standard deviations in images of bar patterns is described in the following references:

Droege, R.T. and R.L. Morin, “A practical method to measure the MTF of CT scanners,” *Med. Phys.*, v. 9, n. 5, 758-760,1982.

Droege, R.T., “A practical method to routinely monitor resolution in digital images,” *Med. Phys.*, v. 10, n. 3, 337-343, 1983.

Droege, R.T. and M.S. Rzeszotarski, “Modulation transfer function from the variance of cyclic bar images,” *Optical Engineering*, v. 23, n. 1, 1984.

Droege, R.T. and M.S. Rzeszotarski, “An MTF method immune to aliasing,” *Med. Phys.*, v. 12, n. 6, 1985.

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12-8 Actions to be taken if specifications are not met

If the required specifications are not met, ensure that all test conditions are met and then retest with the same geometry. If the detector has been allowed to warm up for at least 10 minutes, but less than 30 minutes, allow an additional 20 minutes for the detector to warm up (total of 30 minutes) then repeat the test.

If the results are still below the specifications, a more detailed investigation of the reason should be made. The operator could perform the *CNR and MTF Measurement*, Chap. 1, Sec. 5, or make a measurement of the dimensions (slit camera measurement) or limiting resolution (star pattern measurement) of the focal spot. Information on additional procedures to apply to the evaluation of the focal spot performance can be found in the *Mammography Quality Control Manual* published by the American College of Radiology.

If the above actions do not lead to a satisfactory test result, it is recommended that you contact your GE Medical Systems Service Engineer.

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13 Breast Entrance Exposure, Average Glandular Dose, and Reproducibility

Phantoms suitable for mammographic dosimetry include mammographic phantoms sold by Radiation Measurements, Inc., Model 156; by Fluke Biomedical (Nuclear Associates), Model 18-220; and by Computerized Imaging Reference Systems, Model 15.

Methods for dose calculation and dose conversion tables can be found in the *Mammography Quality Control Manual* published by the American College of Radiology.

If the system does not pass the Breast Entrance Exposure, Average Glandular Dose, and Reproducibility test, you should ensure that all test conditions are met and then repeat the test. If the system still fails, it is recommended that you contact your GE Medical Systems Service Engineer.

14 Artifact Evaluation and Flat Field Uniformity

If the system does not pass the Artifact Evaluation and Flat Field Uniformity test, and the detector has been allowed to warm up for at least 10 minutes, but less than 30 minutes, allow an additional 20 minutes for the detector to warm up (total of 30 minutes) then repeat the test. If the system still fails, it is recommended that you contact your GE Medical Systems Service Engineer.

15 Summary of Mammography Equipment Evaluation

The form given on the following pages may be used to summarize the data acquired during a Senographe DS mammography equipment evaluation (MEE). The detailed data acquired for each test is expected to satisfy MQSA requirements as stated below.

Although *Job Card VF-P03 - Breast Entrance Exposure, Average Glandular Dose and Reproducibility on page 91* in Chapter *2 QC Tests for the Medical Physicist* states that it is only necessary to measure the dose to the phantom for the one image acquisition mode most commonly used clinically to image the standard breast, this limitation is intended to apply only to QC testing. During the MEE, it is recommended that dose measurements be made in all three AOP modes - CNT, STD, and DOSE. Measurements under other conditions may be made at the discretion of the medical physicist.

The applicable MQSA Quality Mammography Standard is:

900.12(e)(10)

Mammography equipment evaluations.

Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

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Summary of Mammography Equipment Evaluation for Senographe DS Mammographic System

Facility Name: _____

Address: _____

_____

_____

Date of Installation		Unit Ser. No.	
Date of Survey		Room ID	
Medical Physicist		Signature	

Test Results

1. Flat Field and Image Quality Checks

Reference: QC tests *Chapter 1*, section *4 Flat Field and Phantom IQ Tests on page 16*

	Pass	Fail
Brightness Non-uniformity		
High Frequency Modulation		
Bad Pixel Verification		
Bad ROI		
SNR Non-uniformity		

Requirement: All Flat Field checks must pass.

	AWS	Printer
No. of Fibers		
No. of Speck Groups		
No. of Masses		

Requirement: 4 largest fibers, 3 largest speck groups, and 3 largest masses must be detected.

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2. CNR and MTF Measurement

Reference: QC tests *Chapter 1*, section *5 CNR and MTF Measurement on page 21*

MTF parallel at 2 lp/mm	
MTF parallel at 4 lp/mm	
MTF perpendicular at 2 lp/mm	
MTF perpendicular at 4 lp/mm	
CNR	

Requirement: MTF at 2 lp/mm > 58%
MTF at 4 lp/mm > 25%.

3. AOP Mode and SNR Check

Reference: QC tests *Chapter 1*, section *7 AOP Mode and SNR Check on page 24*

	Exposure Parameters - AOP, STD Mode			
Acrylic Thickness (mm)	Track/filter	mAs	kV	SNR
25				
50				
60				

AWS software version: _____

Requirement:

AOP B displayed	AWS Version (*)	Acrylic Thick-ness (mm)	Exposure Parameters For AOP STD mode only			SNR
			Track/filter	mAs	kV	
Yes or No	All	25	Mo/Mo	20-60	26	>50
Yes or No	All	50	Rh/Rh	40-90	29	>50
No	V:32.10 and lower	60	Rh/Rh	45-95	31	>50
No	V:43.0 and higher	60	Rh/Rh	45-95	30 or 31	>50
Yes	All	60	Rh/Rh	60-120	30 or 31	>50

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4. Collimation Assessment

Reference: QC tests *Chapter 2*; *Job Card VF-P01 - Collimation Assessment on page 57*

	Pass	Fail
Deviation between X-ray field and light field is less than 2% of SID.		
X-ray field does not extend beyond any side of the image receptor by more than 2% of SID.		
Chest wall edge of the X-ray field extends to the chest wall edge of the image receptor.		
Chest wall edge of compression paddle not visible in image and does not extend beyond image receptor by more than 1% of SID.		

Requirement: All collimation requirements must pass.

5. Evaluation of Focal Spot Performance

Reference: QC tests *Chapter 2*, *Job Card VF-P02 - Evaluation of Focal Spot Performance on page 65*

	Resolution Limit (lp/mm)			
	Bars paral. AC axis		Bars perpr. AC axis	
Anode track	Mo	Rh	Mo	Rh
Contact geometry				
1.5X Magnification				

Requirement: In the contact mode or the 1.5X magnification mode, measurements made with the bars parallel to the anode-cathode axis must be at least 13 lp/mm; measurements with the bars perpendicular to the anode-cathode axis must be at least 11 lp/mm.

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6. Sub-system MTF

Reference: QC tests *Chapter 2*, *Job Card VF-P02A - Sub-System MTF Measurement on page 71*

		Large Focal Spot			Small Focal Spot		
Track	Axis	Freq. (lp/mm)	Pass	Fail	Freq. (lp/mm)	Pass	Fail
Mo	Width	2.09			5		
Rh	Width	2.09			5		
Mo	Length	2.09			5		
Rh	Length	2.09			5		
Mo	Width	3.93			8		
Rh	Width	3.93			8		
Mo	Length	3.93			8		
Rh	Length	3.93			8		

Requirement: All sub-system MTF requirements must pass.

7. Breast Entrance Exposure, Average Glandular Dose, and Reproducibility

Reference: QC tests *Chapter 2*; *Job Card VF-P03 - Breast Entrance Exposure, Average Glandular Dose and Reproducibility on page 91*

Coefficient of Variation of mAs	
Coefficient of Variation of air kerma	

Mean glandular dose to Standard breast	AOP, CNT mode	
	AOP, STD mode	
	AOP, DOSE mode	
other (specify parameters)		

Requirement: The maximum acceptable coefficient of variation for both mAs and air kerma is 0.05. The mean glandular dose to the Standard breast must not exceed 3 mGy (0.3 rad) per view.

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8. Artifact Evaluation and Flat Field Uniformity

Reference: QC tests *Chapter 2*; *Job Card VF-P04 - Artifact Evaluation and Flat Field Uniformity on page 97*

	Pass	Fail
Artifacts are not apparent or are not expected to mimic or obscure clinical information.		

Requirement: Artifact requirements must pass.

9. kVp Accuracy and Reproducibility

Reference: QC tests *Chapter 2*, section *1 Introduction on page 51*,

kVp error at lowest measurable clinical kVp (%)	
kVp error at most commonly used clinical kVp (%)	
kVp error at highest available clinical kVp (%)	

Requirement: The kVp shall be accurate within ± 5 percent of the indicated or selected kVp at each of the above measurement points.

Coefficient of variation at most commonly used clinical kVp setting	

Requirement: At the most commonly used clinical setting of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

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10. Beam Quality Assessment (Half-Value Layer Measurement)
Reference: QC tests *Chapter 2*, section *1 Introduction on page 51*.

	Pass	Fail
Half-value layer equals or exceeds minimum allowed under MQSA.		

Requirement: Half-value layer must equal or exceed MQSA minimum value.

11. Radiation Output
Reference: QC tests *Chapter 2*, section *1 Introduction on page 51*,

	Value	Units
Radiation output		

Requirement: The system shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) under specified conditions.

	Pass	Fail
Output maintained for at least 3.0 sec.		

Requirement: The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

12. Mammographic Unit Evaluation
Reference: QC tests *Chapter 2*, section *1 Introduction on page 51*.

	Pass	Fail
System meets requirements for motion of tube-image receptor assembly.		
System meets requirements for compression paddle decompression.		

Requirement: The system shall meet the MQSA requirements for motion of the tube-image receptor assembly and for compression paddle decompression.

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Revision History

This page is intentionally left in English in the translated versions.

Note for the Technical Writer:
This publication is contained in a multibook "Master Folder". It is a slave publication.
To maintain this publication, it is mandatory to use "Master Folder" 5305753-x-899 as the Frame-Maker source.
The "Master Folder" contains a "Read Me" which explains how to proceed.

File Name	DATE	REASON FOR CHANGE
5133453-1xx rev. 1	July 26, 2005	Initial release for product Senographe DS, Nephtys Milestone M5A. Based on 2404641-1xx rev. 2 with addition of Automated Repeat and Reject analysis feature, incuding PC Tool for Repeat Analysis.
5133453-2-1xx rev.1	February 10, 2006	Release for product Senographe DS, Nephtys Milestone M5B. Modifications and corrections including revised monitor cleaning instructions for consistency with Senographe Essential Sirius M3A. Added definition of *Change in CNR* (p 19) (SPR EURge43401). Added new Job Card VF-P02A and Chart 2A (Sub-system MTF measurement without film), and associated references in the Guidance chapter (section 12) and elsewhere.
5133453-3-1xx rev.1	May 22, 2007	Release for product Senographe DS, Nephtys Milestone M49. Page 13, chapter 1, section 1: modification of text to introduce data back-up onto CD-R media. Pages 24: chapter 1, section 7 AOP Mode and SNR Check. Modification of action limit parameters (30 or 31 kV according to AW software release. Page 108: Summary of Mammography Equipment Evaluation - AOP Mode and SNR Check. Modification of action limit parameter (30 or 31 kV according to AW software release). Addresses of GE Service offices are removed from document.

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File Name	DATE	REASON FOR CHANGE
5133453-4-1EN rev.1	September 4, 2007	Release for product Senographe DS, Nephtys Milestone M4(10). Page 9, Foreword, section 2: modification of "Alternative Standard on use of Test Result" paragraph. Page 10, item (i)(A)(11) Sub-system MTF Measurement is appended to the statement of the "Alternative Standard on the Use of Test Results". Pages 61, Chart 1: "Difference" changed by "Deviation" for homogenization of terms used in the tables. Page 107, Summary of Mammography Equipment Evaluation for Senographe DS Mammographic System, section 4 - Collimation Assessment: Correction of table row "Chest wall edge of the X-ray field extends to the chest wall edge of the image receptor".
	October 24, 2007	Litchi project Before sending to Litchi LocUI translations: - Cleaning paragraphs and cross references according “Loc_Templates_071115_FM_Litchi”. - Sent to translation in EL, TR, HU, PL, RU, DA, FI, NL, NO, SV.
	December 12, 2007	Litchi-P project Sent to translation in PT-PT.
5305756-2-899-1EN Rev 1A_080304	February 19, 2008	Draft for submission to FDA for product Senographe DS: Introduction of AOP FlexDose feature See Read Me for a detailed table of evolutions from the previous publication Validation after PMA submission
5305756-2-899-1EN Rev 1	February 9, 2009	Product: Senographe DS Technical Release: Nephtys post M4(13) Update of 5305756-1-899-1EN Rev 1A_080304 Main changes: Becomes MQSA compliant

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